

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE OCUGEN, INC. SECURITIES
LITIGATION

Master File No.: 2:21-cv-02725-CDJ

**CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF
FEDERAL SECURITIES LAWS AND JURY DEMAND**

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Lead Plaintiff Andre Galan Bernd Benayon (“Plaintiff”), individually and on behalf of all others similarly situated, alleges the following based upon personal knowledge as to allegations concerning himself and, as to all other matters, upon the investigation of counsel, which included, among other things, a review of U.S. Securities and Exchange Commission (“SEC”) filings by Ocugen, Inc. (“Ocugen” or the “Company”) and securities analyst reports, press releases, and other public statements issued by, or about, the Company and Bharat Biotech International Limited (“Bharat”). Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. This is a federal securities class action on behalf of a Class consisting of all persons who purchased or otherwise acquired Ocugen securities between February 2, 2021 and June 9, 2021, inclusive (the “Class Period”), seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Ocugen was a failing biopharmaceutical company, attempting to develop gene therapies to treat various eye diseases. Between 2013 and 2020, Ocugen did not earn any material revenues and it had never successfully commercialized a product. By mid-2020, as the COVID-19 pandemic ravaged the United States, things were only getting worse for the Company. On June 5, 2020, Ocugen terminated five of its fifteen employees after abandoning one of its most promising product candidates. Soon afterwards, on July 14, 2020, Ocugen common stock, which traded on the NASDAQ Stock Exchange, closed at just \$0.196 per share.

3. On November 6, 2020, at the same time Ocugen was facing delisting for failure to maintain a minimum \$1.00 per share stock price, it issued a “going concern” warning in its SEC Form 10-Q stating, “there is substantial doubt about the Company’s ability to continue as a going

concern within one year after the date that these condensed consolidated financial statements are issued.” On December 21, 2020, Ocugen’s common stock closed at \$0.294 per share.

4. Ocugen’s fortunes then literally changed overnight. On December 22, 2020, on the heels of the U.S. Food and Drug Administration (“FDA”) authorizing Pfizer/BioNTech’s and Moderna’s COVID-19 vaccines, Ocugen announced that it had executed a letter of intent with Bharat, an Indian multinational biotechnology company, to bring Bharat’s Indian-developed and manufactured COVID-19 vaccine, COVAXIN™, to the U.S. market. The Company boasted that the “collaboration leverages Ocugen’s vaccine expertise, and its R&D and regulatory capabilities in the [U.S.].” Although details of the agreement were still being negotiated, Ocugen claimed that it had already “assembled a Vaccine Scientific Advisory Board featuring leading academic and industry experts to evaluate the clinical and regulatory path to approval in the [U.S.] market.”

5. In response, the price of Ocugen’s common stock increased from \$0.294 per share on December 21, 2020, to \$0.805 per share on December 22, 2020. The next day, on December 23, 2020, Ocugen stock closed at \$2.60 per share which meant, after more than a year, Ocugen finally met the NASDAQ’s minimum \$1.00 per share requirement.

6. On February 2, 2021, the first day of the Class Period, Ocugen announced that it had executed a definitive agreement with Bharat for the commercialization of COVAXIN in the U.S. Ocugen claimed that it had already begun engaging with the FDA regarding COVAXIN authorization via the agency’s fast-track emergency use authorization (“EUA”) process, which was the same FDA pathway by which Pfizer/BioNTech’s and Moderna’s COVID-19 vaccines were authorized on December 11 and December 18, 2020, respectively.

7. That Ocugen would seek an EUA for COVAXIN, and not a biologics license application (“BLA”), was significant because the traditional BLA pathway would only increase

the timeline for U.S. approval and commercialization. Indeed, in connection with Ocugen's February 2, 2021 press release, the Company told securities analysts that it expected to receive FDA authorization and distribute 100 million doses of COVAXIN in the U.S. during of 2021.

8. The targeting of 100 million COVAXIN doses sold in the U.S. in 2021 was premised upon a quick FDA EUA approval which would necessarily require the FDA accept Bharat's Indian Phase 3 data, and not require Ocugen to conduct further U.S. studies. If the FDA required Ocugen to pursue the full BLA route for approval or otherwise undertake additional U.S. studies, it would significantly delay any COVAXIN roll out, likely delaying FDA authorization or approval and any associated revenues by a year or more.

9. Ocugen's positive announcements caused its stock price to soar, increasing 80%, from a close of \$1.81 per share on February 1, 2021 to \$3.26 per share on February 2, 2021.

10. Shortly thereafter, on February 5, 2021, Ocugen filed with the SEC and posted on its website a slide presentation claiming that the Company was in "pre-EUA discussions with FDA," it was "[t]arget[ing] 100M Doses/Year Starting 2021," it "[p]lanned [its] EUA Filing with FDA" in "1H 2021," COVAXIN shots were expected to be available in the U.S. beginning in "1H 2021," and that "COVAXIN [is a] Vaccine candidate for the [U.S.] market with potential for significant revenues this year." Defendants would repeat these same claims throughout the entire Class Period.

11. In response, the price of the Company's common stock tripled, from a close of \$5.25 per share on Friday, February 5, 2021, to a close of \$15.81 per share on Monday, February 8, 2021. The \$15.81 per share closing price was 54 times the \$0.29 per share price just seven weeks earlier, prior to the initial announcement of Ocugen's collaboration with Bharat.

12. Defendants took full advantage of the investor enthusiasm they had created. During the first four months of 2021, the Company netted more than \$119 million from sales of its common stock, which was more capital than it had raised in its previous *seven years* of existence.

13. Throughout the Class Period, Defendants continued to promote Ocugen's stock by assuring investors that they expected to submit an EUA application to the FDA in the first half of 2021, receive authorization within weeks thereafter, and generate significant revenues in 2021 by selling up to 200 million doses of COVAXIN in the U.S.

14. Defendants also sought to address potential concerns about their timeline by telling investors that an EUA could be based upon the Indian Phase 3 trials, without the need for time-consuming U.S. trials. For example, on March 15, 2021, defendant Shankar Musunuri ("Musunuri"), Ocugen's Co-Founder, Chief Executive Officer ("CEO"), and Chairman, announced that the FDA was "fine with the way the [Phase 3 Indian study's] interim analysis is being done." On March 31, 2021, Defendants reassured investors that it was unlikely that U.S. trials would be necessary because the Indian data would be "translatable" to the U.S. due to the quality of the studies and the "diversity" of the trial participants. Defendant Musunuri later specifically assured investors that Ocugen was "following FDA guidance on EUA[s]" and that the FDA had not said that it wanted any U.S. data prior to allowing the COVAXIN EUA submission to go forward.

15. On May 3, 2021, Musunuri unloaded 195,809 shares of his personally held Ocugen common stock, realizing proceeds of \$2,788,320. This was his first *ever* sale of Ocugen stock.

16. Defendants' Class Period statements regarding Ocugen's development of COVAXIN for the U.S. market were materially false and misleading, and omitted facts necessary to make their statements not misleading. *Defendants were not following the FDA's industry*

guidance for COVID-19 vaccine EUAs, as investors were led to believe. Among other things, the FDA’s industry guidance, and the agency’s interpretation thereof, repeatedly stressed the need for studies on the target U.S. population, including a diverse study population of representative numbers of participants who were Hispanic, African American, and other ethnicities. And the FDA repeatedly reiterated that it was strictly following, and would continue to strictly apply and follow, its EUA procedures and guidance. Even the Indian developer of COVAXIN, Bharat, acknowledged early on that U.S. studies would be necessary prior to the vaccine being authorized in the U.S.

17. Because Ocugen was not following FDA industry guidance, it would not receive an EUA for COVAXIN, and any FDA authorization or approval of the vaccine would likely be delayed by up to a year, if not more, while U.S. trials were undertaken. Accordingly, Defendants *knew* their timelines for COVAXIN authorization and commercialization were patently unreasonable, as was any expectation that the Company would earn significant COVAXIN revenues in 2021.

18. On May 25, 2021, the FDA revised its industry guidance for COVID-19 vaccine EUAs, effectively shutting the door on EUAs for COVID-19 vaccines for which developers failed to “engage[] in an ongoing manner with the Agency *during the development of their manufacturing process and clinical trials program.*”¹ Instead, sponsors of vaccines such as COVAXIN, which was developed, studied, and manufactured out of sight of the FDA in India, would need to seek full FDA approval through the standard, more rigorous, and more time-consuming BLA process.

19. Defendants responded the very next day with a press release blatantly misrepresenting the new industry guidance and falsely assuring investors that Ocugen was “on

¹ All emphasis is added unless otherwise noted.

track” to submit its EUA in June. Defendants suggested the revised guidance was not even applicable to an inactivated virus vaccine like COVAXIN and, at any rate, the guidance did not “raise[] any concerns” because Ocugen had “been in discussions with the FDA since late last year.” In fact, according to Defendants, “the FDA’s new guidance confirms that Ocugen continues to meet all criteria for submission of an EUA.”

20. Defendants’ assurances had their intended effect, causing the price of Ocugen’s common stock to jump from a close of \$7.66 per share on May 26, 2021, to a close of \$8.71 per share the next day.

21. Shortly thereafter, on June 7 and 8, 2021, Musunuri unloaded 30,558 more shares of his personally held Ocugen common stock, realizing another \$335,216 in proceeds.

22. On June 10, 2021, before the market opened, Defendants’ con came to an end when the Company issued a press release stating that, upon the FDA’s recommendation, it would no longer pursue an EUA for COVAXIN, that it would instead pursue a more time-consuming BLA, and that additional trials would be necessary for FDA approval. Of course, contrary to what investors were told during the Class Period, under the FDA’s industry guidance, FDA authorization of COVAXIN through the fast-track EUA process was always exceedingly unlikely and, in any event, COVAXIN authorization or approval could only occur after the completion of time-consuming U.S. trials.

23. On this news, the Company’s share price plummeted 28% from a close of \$9.31 per share on June 9, 2021 to \$6.69 per share on June 10, 2021.

24. The following day, on June 11, 2021, Ocugen’s partner, Bharat, admitted that the longer BLA path was inevitable for some time, stating, “the [FDA] had earlier communicated that no new EUA would be approved for new COVID-19 vaccines.” Defendant Musunuri would later

belatedly concede that, for an EUA, “[t]ypically, you would need a clinical study with a US demographic” because “[i]t is important to collect the [U.S.] data from a safety perspective, because different groups may have different reactions.” Unfortunately, these admissions came too late for Class members who collectively lost hundreds of millions of dollars because of Defendants’ materially false and misleading statements.

25. Ocugen is currently undertaking a U.S. COVAXIN study “to establish whether the immune response experienced by participants in a completed Phase 3 efficacy trial in India is similar to that observed in a demographically representative, healthy adult population in the U.S. who either have not been vaccinated for COVID-19 or who already received two doses of an mRNA vaccine at least six months earlier.” According to ClinicalTrials.gov, the study has an estimated primary completion date of September 1, 2023.

II. JURISDICTION AND VENUE

26. The claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5. This Court has jurisdiction over the subject matter of this action under § 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States of America.

27. Venue is proper in this District under § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b)-(d). Ocugen is headquartered in this District, and many of the acts charged herein, including the dissemination of materially false and misleading information, occurred in substantial part in this District.

28. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, without

limitation, the U.S. mail, interstate telephone and other electronic communications and the facilities of a national securities exchange.

III. PARTIES

29. Plaintiff, as set forth in the previously filed certification (*see* ECF No. 10-4), and incorporated by reference herein, purchased Ocugen securities during the Class Period and has been damaged thereby.

30. Defendant Ocugen is a Delaware corporation with its principal executive offices located at 263 Great Valley Parkway, Malvern, Pennsylvania 19355. Ocugen common stock trades on the NASDAQ under the ticker symbol “OCGN.”

31. Defendant Musunuri, Ocugen’s Co-Founder, was, at relevant times, the Company’s CEO and Chairman. As of March 31, 2021, Musunuri beneficially owned 2,638,745 shares of Ocugen common stock, or 1.4% of the Company’s outstanding shares.

32. Defendant Bruce D. Forrest (“Forrest”) was, at relevant times, a member of Ocugen’s Vaccine Scientific Advisory Board, which was tasked with evaluating COVAXIN’s “clinical and regulatory path to approval in the US.” Forrest became the Company’s Acting Chief Medical Officer (“CMO”) in mid-May 2021. Forrest has a long history with Musunuri with their overlapping employment at Pfizer/Wyeth spanning more than a decade, through early 2010. Both claim to have worked on Pfizer/Wyeth’s Prevnar 13 vaccine, with Musunuri stating he was “Global Operations Team Leader” for “the most successful launch in vaccine history, Prevnar 13®,” and Forrest acting as “Senior Vice President of Wyeth Pharmaceuticals” “leading both clinical and pharmaceutical science development contributing to the development of Prevnar 13®.”

33. Musunuri and Forrest are collectively referred to as the “Individual Defendants.” The Individual Defendants and Ocugen are the “Defendants.”

34. As officers and controlling persons of a publicly held company whose securities are registered with the SEC pursuant to the Exchange Act and trade on the NASDAQ, which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's business, operations, and prospects. In addition, the Individual Defendants each had a duty to correct any previously issued statements that had become materially misleading or untrue, so that investors were provided with accurate and complete information. Defendants' false and misleading statements, misrepresentations, and omissions during the Class Period violated these specific requirements and obligations.

IV. FACTUAL BACKGROUND

A. The COVID-19 Pandemic/Operation Warp Speed

35. On May 15, 2020, in response to the COVID-19 pandemic, the Trump Administration announced Operation Warp Speed, or "OWS," the administration's program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Dr. Moncef Slaoui was appointed OWS's Scientific Director and General. Gustave F. Perna was appointed Chief Operating Officer. The President described Dr. Slaoui as "one of the most respected men in the world in the production and formulation of vaccines" having "helped create fourteen new vaccines . . . in ten years during his tenure in the private sector."

36. Operation Warp Speed sought to encourage private and public partnerships to enable faster approval and production of vaccines during the COVID-19 pandemic. OWS was initially funded with about \$10 billion from the CARES Act (Coronavirus Aid, Relief, and Economic Security) passed by the United States Congress on March 27, 2020. Its stated goal was to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021.

37. OWS was a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS would coordinate Health and Human Services-wide efforts, including the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership for vaccine and therapeutic development, the NIH Rapid Acceleration of Diagnostics (RADx) initiative for diagnostic development, and work by BARDA.

38. The development plan included ongoing participation by the government in developing and executing select vaccine candidates' clinical trial programs. As described by the HHS:

DEVELOPMENT: To accelerate development while maintaining standards for safety and efficacy, OWS has been selecting the most promising countermeasure candidates and providing coordinated government support.

Protocols for the demonstration of safety and efficacy are being aligned, which will allow these harmonized clinical trials to proceed more quickly, and the protocols for the trials will be overseen by the federal government (NIH), as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of vaccines and therapeutics at industrial scale well before the demonstration of efficacy and safety as happens normally. This increases the financial risk, but not the product risk.

39. OWS's COVID-19 vaccine plan involved first identifying fourteen promising vaccine candidates from more than 100 which were in development at the time. The fourteen candidates would then be narrowed to about eight candidates, representing the most promising candidates from a range of technology options, which would then go through further testing in

early-stage clinical trials. Large-scale randomized trials for the demonstration of safety and efficacy would then proceed for the most promising candidates.

40. Among OWS's criteria for choosing its initial candidates was that they employ one of four vaccine-platform technologies judged by OWS to be the most likely to yield a safe and effective vaccine against COVID-19: (1) the mRNA platform; (2) the replication-defective live-vector platform; (3) the recombinant-subunit-adjuvanted protein platform; and (4) the attenuated replicating live-vector platform. OWS sought to build a diverse project portfolio that included vaccine candidates based on different platform technologies which would mitigate the risk of failure due to safety, efficacy, industrial manufacturability, or scheduling factors.

41. One older vaccine-platform technology, inactivated virus, was conspicuously absent from OWS's portfolio. While some other countries focused their efforts on developing such vaccines, *OWS made a conscious decision not to include inactivated virus vaccines in its development program.*

42. OWS's decision was due to concern about vaccine hesitancy among the U.S. population and the need to maintain public confidence in the safety of any COVID-19 vaccine approved by the FDA. Although inactivated virus vaccines had a long track record, in 1955, an infamous accident, known as the Cutter incident, involving an inactivated poliovirus vaccine, reportedly caused 40,000 cases of polio, left 200 children paralyzed, and killed 10. Francis Collins, NIH Director, told a Senate subcommittee in July 2020 that "I could reassure you and the American people that that strategy of trying to administer a killed vaccine is not currently being pursued for [COVID-19] because of those risks."

43. Of the original eight vaccine candidates in OWS's portfolio, six partnerships were executed with the following companies: Pfizer/BioNTech, Moderna, Johnson & Johnson,

Novavax, AstraZeneca, and Sanofi/GSK. Information about the vaccine candidates and the government contracts awarded is reflected in the following Congressional Research Service chart (as of March 1, 2021):²

Table 1. Vaccine Candidates Supported by BARDA and Other Federal Agencies						
Company	Type	Contract Value	Specifications	Doses per Person	Current Phase (Preliminary Effectiveness – U.S. Strain)^a	Storage
Pfizer/BioNTech	mRNA ^b	\$5.97B	300 million doses	2	Phase II/III (95%) EUA Issued	Ultra cold storage (-70° C)
Moderna	mRNA	\$4.94B	300 million doses	2	Phase III (94.5%)	Cold storage (6 mos, -20° C)
		\$954M	Development		EUA Issued	Refrigerator (30 days, -2° to -8° C)
AstraZeneca/ Oxford Univ.	Viral Vector ^c	\$1.2B	300 million doses	2	Phase II/III (70%)	Refrigerator (-2° to -8° C)
Johnson & Johnson (Janssen Pharmaceuticals)	Viral Vector	\$1B	100 million doses	1	Phase III (72%)	Refrigerator (3 mos, -2° to -8° C)
		\$456M	Development		EUA Issued	
Novavax	Protein ^d	\$1.6B	100 million doses	2	Phase III (95.6%)	Refrigerator (-2° to -8° C)
Sanofi/GSK	Protein	\$2.04B	100 million doses	2	Phase I/II	Refrigerator (-2° to -8° C)
		\$30.8M	Development			
Merck/IAVI ^e	Viral Vector	\$38M	Development ^f	1	DISCONTINUED	N/A

44. Ultimately, OWS invested some \$18 billion in developing the various COVID-19 vaccines, with much of that money going towards pre-purchasing hundreds of millions of doses so they would be at the ready when an FDA authorization came through.

B. The FDA Was Concerned About COVID-19 Vaccine Hesitancy

45. A safe and effective COVID-19 vaccine would be of limited benefit if the U.S. population refused to be vaccinated due to safety concerns. A Gallup poll in the summer of 2020 found that 35% of respondents would not be vaccinated even if the vaccine was FDA approved and free. A September 2020 poll found that 62% of respondents believed that political pressure

² <https://crsreports.congress.gov/product/pdf/IN/IN11560> (last visited 6/13/2022).

would lead the FDA to rush approval of a coronavirus vaccine without ensuring that it was safe and effective. With certain politicians touting accelerated timelines for COVID-19 vaccines—potentially ending in an EUA before the November 2020 election—public confidence in the FDA’s approval process had taken a hit.

46. FDA officials pushed back, insisting, “[w]e will rely upon data and science when it comes to that decision about an EUA.” Peter Marks, who ran the FDA division that oversees vaccine approval, vowed that he would resign if the current administration pushed through a vaccine that was not clearly safe and effective.

47. On September 8, 2020, CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer, and Sanofi signed a joint statement pledging they would not file for regulatory approval of experimental COVID-19 vaccines until the immunization was shown to work safely through late-stage clinical testing. All nine CEOs signed the following pledge:

We, the undersigned biopharmaceutical companies, want to make clear our on-going commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.

The safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, such as the [FDA]. FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. FDA’s guidance and criteria are based on the scientific and medical principles necessary to clearly demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.

Following guidance from expert regulatory authorities such as FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we pledge to:

- Always make the safety and well-being of vaccinated individuals our top priority.
- Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.
- Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.
- Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.

48. Even after the pledge, however, U.S. vaccine hesitancy continued to be a serious concern. And those involved in OWS continued to assure the public that no corners would be cut and that COVID-19 vaccine approvals would not be made or rushed due to outside pressure.

C. The FDA's Standard Vaccine Approval Process

49. Under the Federal Food, Drug, and Cosmetic Act, typically, the FDA must approve a new vaccine before it may be lawfully sold. To obtain FDA approval, a new vaccine must undergo an extensive application and approval process. A sponsor seeking approval of its vaccine must submit evidence that the product is both safe and effective under the conditions prescribed in the proposed labeling.

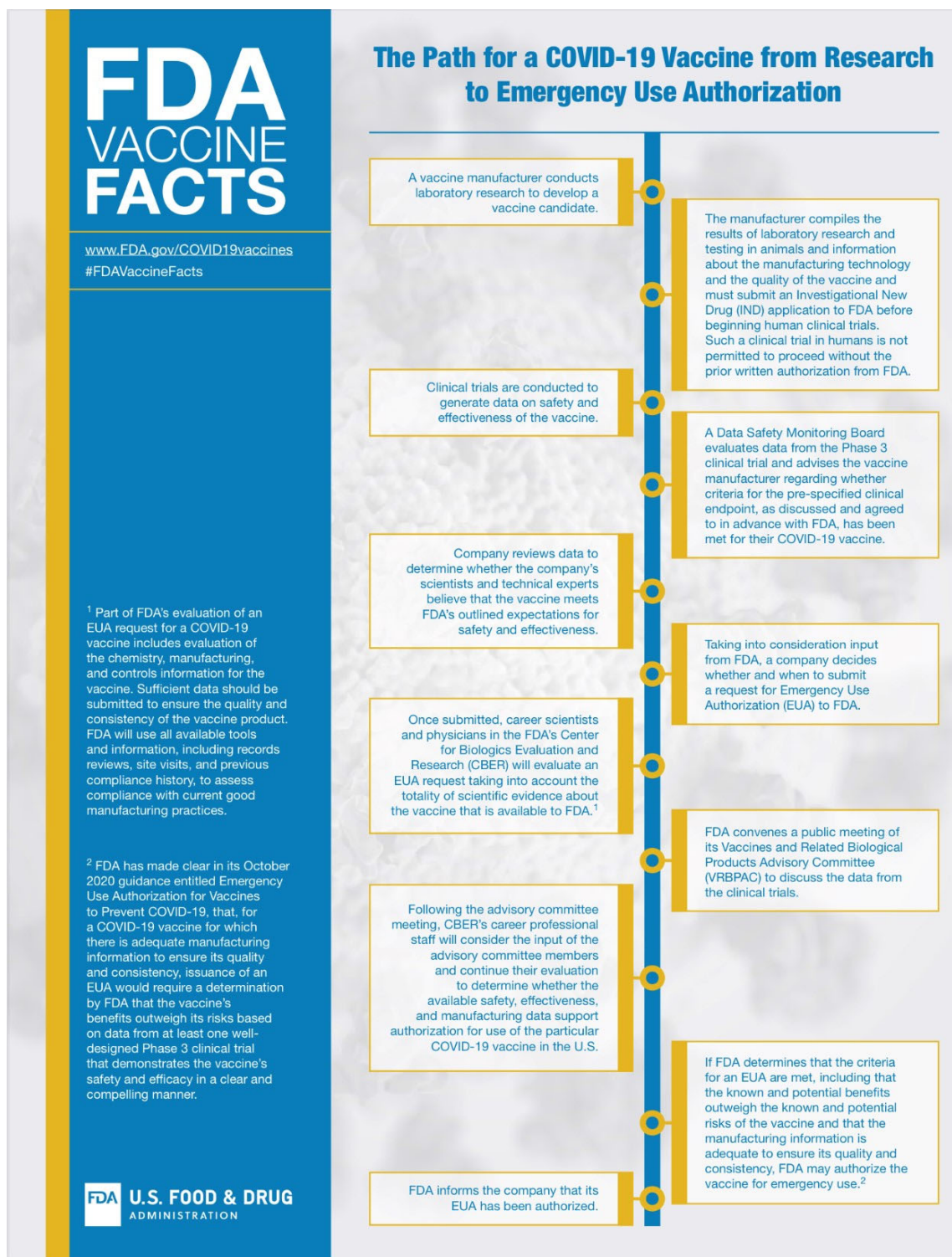
50. After initial laboratory and animal tests, vaccines enter Phase 1 human trials that typically have about 20 to 100 people and primarily analyze safety and immune responses. Phase 2 studies are larger versions of Phase 1 trials. Phase 3 studies attempt to determine whether a vaccine works by comparing people who receive it with those who are given a placebo shot and, over several months or years, seeing how many in each group get infected. For COVID-19 vaccines, these trials involve between 10,000 to 60,000 people and require a total of about 150 cases of disease to determine whether a candidate works. Once the trial endpoints are met, a

vaccine developer seeking FDA approval would file a BLA; the FDA's Vaccines and Related Biological Products Advisory Committee would review the data at a public meeting, and then vote on whether the vaccine should receive approval—a recommendation the FDA normally follows. The approval process, which includes inspecting the vaccine's manufacturing plants, will often take one year.

D. The FDA's COVID-19 Vaccine EUA Process and Industry Guidance

51. When necessary to respond to “an actual or potential emergency,” the FDA may issue an EUA for unapproved drugs, or for unapproved uses of approved drugs, under certain circumstances and for the duration of the emergency, provided that certain statutory criteria are met. Among other criteria, an EUA requires that the drug's known and potential benefits outweigh its known and potential risks. On March 27, 2020, HHS declared that circumstances existed justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic.

52. In late 2020, the FDA posted on its website the following infographic describing its COVID-19 vaccine authorization process from initial vaccine research to the issuance of an EUA:



53. In May 2020, the FDA issued industry guidance entitled “COVID-19: Developing Drugs and Biological Products for Treatment or Prevention, Guidance for Industry.” In a section entitled “Safety Consideration,” the guidance noted that “[i]t is important to include a broad

population of subjects in adequate and well-controlled clinical trials to generate a safety database that will best inform the safe use of the drug.” Similarly, in a section concerning trial populations for COVID-19 vaccine studies, the guidance highlighted the need for a diverse population of study participants:

- Clinical trials should include persons at high risk of complications such as the elderly, persons with underlying cardiovascular or respiratory disease, diabetes, chronic kidney disease, or other comorbidities, and immunocompromised persons (e.g., HIV-infected patients, organ transplant recipients, or patients receiving cancer chemotherapy).
- COVID-19 disproportionately affects adults, including older individuals. The geriatric population should be appropriately represented in clinical trials. Sponsors should consider conducting trials in nursing homes or other elder care facilities.
- Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.

54. In June 2020, the FDA issued a document entitled “Development and Licensure of Vaccines to Prevent COVID-19, Guidance for Industry,” which was meant “to assist sponsors in the clinical development and licensure of vaccines for the prevention of COVID-19.” The guidance stated the following with respect to an EUA:

In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA would be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.

55. In a section on “Key Considerations” for clinical trials, the guidance document described the need for vaccine sponsors to work with the FDA at all stages of vaccine development:

- Regardless of whether clinical development programs proceed in discrete phases with separate studies or via a more seamless approach, an adequate body of data, including data to inform the risk of vaccine-associated ERD, will be needed as clinical development progresses to support the safety of vaccinating the proposed

study populations and number of participants and, for later stage development, to ensure that the study design is adequate to meet its objectives.

- FDA can provide early advice, and potentially concurrence in principle, on plans for expedited/seamless clinical development. However, sponsors should plan to submit summaries of data available at each development milestone for FDA review and concurrence prior to advancing to the next phase of development.

56. In the “Key Considerations” section regarding Trial Populations, the guidance document described the need to design trials such that it may be determined that the vaccines are safe and effective for “diverse populations.” It stated, in part:

- FDA encourages the inclusion of diverse populations in all phases of vaccine clinical development. This inclusion helps to ensure that vaccines are safe and effective for everyone in the indicated populations.
 - FDA strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.

57. In October 2020, the FDA issued additional industry guidance “to provide sponsors of requests for [EUA] for COVID-19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act [] for an investigational vaccine to prevent COVID-19 for the duration of the COVID-19 public health emergency.” In the “Background” section of the document, the FDA stated that its guidance would apply to all types of COVID-19 vaccines in development:

This guidance describes FDA’s current recommendations regarding the data and information needed to support the issuance of an [EUA] under section 564 of the FD&C Act (21 U.S.C. 360bbb-3) for an investigational vaccine to prevent COVID-19, including chemistry, manufacturing, and controls information (CMC); nonclinical data and information; and clinical data and information, as well as administrative and regulatory information. In addition, the guidance provides recommendations regarding key information and data that should be submitted to a relevant investigational new drug application (IND) or cross-referenced master file (MF) prior to submission of an EUA request in order to facilitate FDA’s complete and timely review of such a submission, including convening the Vaccines and Related Biological Products Advisory Committee (VRBPAC). This guidance also discusses FDA’s current thinking regarding the circumstances under which the issuance of an EUA for a COVID-19 vaccine would be appropriate, providing

additional context to the discussion regarding EUAs in the guidance for industry entitled “Development and Licensure of Vaccines to Prevent COVID-19” (Ref. 1).

These recommendations are specific to COVID-19 vaccines, which are complex biological products that are intended to be administered to millions of individuals, including healthy people, to prevent disease. These vaccines have the potential for broad use under an EUA. The recommendations in this guidance are not necessarily applicable to drugs and biological products intended for treatment of COVID-19, for which there may be significantly different considerations under the standard set forth in section 564 of the FD&C Act (21 U.S.C. 360bbb-3), reflecting the products’ characteristics and anticipated clinical uses.

58. The October 2020 guidance specifically set forth the statutory requirements that needed to be met in order for the FDA to issue an EUA for a COVID-19 vaccine:

Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)) (Ref. 3):

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA will be made on a case by case basis ***considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.***

FDA acknowledges that an EUA for a COVID-19 vaccine may be requested to allow for the vaccine’s rapid and widespread deployment for administration to millions of individuals, including healthy people, potentially following interim

results from one or more clinical trials meeting prespecified success criteria described in the analysis plan submitted to FDA. In this scenario, for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks ***based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.***

59. The October 2020 guidance states that vaccine candidate sponsors “contact the Center for Biologics Evaluation and Research’s (CBER’s) Office of Vaccines Research and Review (OVRR) ***as early in development as possible*** to discuss expectations and considerations for the sponsor’s particular vaccine.” The FDA also recommended that “vaccine sponsors ***engage in early communication with CBER’s Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality to discuss facility issues related to manufacturing*** of the particular vaccine.”

60. On October 22, 2020, VRBPAC met in open session to discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19. VRBPAC—which is made up of fifteen voting members knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry—provides advice to the FDA as to whether it should authorize or approve new drugs.

61. Thus, for any COVID-19 vaccine candidate seeking an EUA, VRBPAC is tasked with reviewing the supporting data at a public meeting, then voting on whether the vaccine should receive authorization—a recommendation the FDA normally follows. Because a recommendation for FDA authorization almost certainly results in FDA EUA approval, VRBPAC’s guidance,

advice, views, and opinions are essential to vaccine sponsors' understanding of the EUA process. For this reason, the FDA promptly posted all information concerning the meeting, including slide presentations, presentation materials, transcripts, and a video of the webcast, on its website.

62. In the briefing document for the October 22, 2020 meeting, the FDA stated that the topics to be covered at the VRBPAC meeting would include discussion of “studies, in addition to those recommended in the June 2020 guidance for industry, that should be conducted, pre- and/or post-licensure, to evaluate the safety and efficacy of COVID-19 vaccine candidates, including in special populations (e.g., pediatric populations and pregnant women), and to further evaluate the immunogenicity and duration of effectiveness of these vaccines.”

63. In discussing COVID-19 vaccine development, Dr. Hilary Marston, medical officer and policy advisor for pandemic preparedness in the Office of the Director at NIAID, emphasized the importance of enrolling trial participants that are most affected by COVID-19 including those that are part of underserved minority communities. She said in relevant part:

Next, enrolling those at highest risk of infection and severe disease, so it is critical that, at the end of these trials, we have reliable, interpretable data on the safety and efficacy of these vaccines in those who are hardest hit by the pandemic. So who is that? We know, as described by the prior speaker, that those individuals who are in older age groups are at risk for severe disease and those individuals who have specific comorbidities. In addition, we know that individuals from underserved minorities are hit harder by this pandemic, both in terms of infection and in terms of severe disease and, indeed, death.

So we know that we need specific information in these groups. Our trials have parameters that are explicit on enrollment of volunteers with these individual risk factors, so, for example, whether it's individuals over age 65, people with comorbidities, or people of specific underserved minorities. And in order to do the latter, we've been working hard on proactive community engagement activities, and this really has been a top priority for NIH leadership at the highest levels. ***These measures are critical to the success of the trials themselves, but they're also going to allow assessment of safety and efficacy in the populations that are at highest risk.*** And we know that's going to be essential for future acceptability of these vaccines.

64. Dr. Marsten also spoke of the importance of transparency with respect to the diversity of trial participants so as help address vaccine hesitancy. She stated:

There is a good deal of work to be done in this area. We know that a good portion of the U.S. public is skeptical of these vaccines and not jumping to take them once approved, at least at present. So what are we doing about it?

So first, maintaining safeguards for volunteers and for the study conduct, we are taking that very seriously as discussed earlier in the presentation. We're engaging directly with stakeholders from underserved minorities and that are hardest hit by the pandemic. And we're communicating the roles that entities like the NIH, like the VRBPAC, like regulatory bodies play in the careful evaluation and potential authorization of vaccines.

And importantly, we're committing to transparency. So the companies have made some real strides in this area, posting their final protocols, sharing enrollment data on an ongoing basis, including enrollment by race/ethnicity. And the prompt sharing of results will also be a priority for us – prompt sharing of full results.

65. Robert Johnson of BARDA also spoke at length about the trials supporting an EUA and the need for “good diversification across enrollment in the trial.”

66. Dr. Doran Fink of the FDA echoed the need for diversity in the trials' populations and pointed out that the requirement is already encompassed in the FDA EUA guidance:

In our guidance document, we've stated that clinical trial to support licensure should enroll adequate numbers of subjects representing populations most affected by COVID-19. These include racial and ethnic minorities, elderly individuals, and individuals with comorbidities associated with increased risk of severe COVID-19.

* * *

Right. So, you know, we have not ever had requirements for demographic composition of data to support licensure of a vaccine and I think it would be very difficult to outline such requirements for EUA. Now, that being said *I think we all understand, and agree with, and support the importance of having a diverse study population that is able to provide safety and effectiveness data across the demographic spectrum. That is the goal.*

And so one way in which our regulatory action can help to ensure that the vaccines being deployed are safe and effective for the entire population for which it is authorized is to make sure that the entire population for which it is authorized

actually has data that supports the safety and effectiveness. ***So we will be looking very closely at an EUA application to see where the gaps are in terms of demographic representation.***

67. In November 2020, the FDA issued industry guidance entitled “Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry.” The guidance described the need for diverse populations in clinical trials, stating, “Sponsors should enroll participants who reflect the characteristics of clinically relevant populations with regard to age, sex, race, and ethnicity.[] Inadequate participation and/or data analyses from clinically relevant populations can lead to insufficient information pertaining to medical product safety and effectiveness for product labeling.” It further explained:

- Inclusion of racial and ethnic minorities in clinical trials and the analysis of clinical trial data by race and ethnicity. Differences in response to medical products (e.g., pharmacokinetics, efficacy, or safety) have been observed in racially and ethnically distinct subgroups of the U.S. population.[] These differences may be attributable to intrinsic factors (e.g., genetics, metabolism, elimination), extrinsic factors (e.g., diet, environmental exposure, sociocultural issues), or interactions between these factors.[] Analyzing data on race and ethnicity may assist in identifying population-specific signals.[] Therefore, FDA recommends that for drugs and biologics, sponsors include a plan for inclusion of clinically relevant populations no later than the end of the Phase 2 meeting.[]

68. On February 22, 2021, the FDA issued additional industry guidance “to provide sponsors of requests for [EUA] for COVID-19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act [] for an investigational vaccine to prevent COVID-19 for the duration of the COVID-19 public health emergency.” In the “Background” section of the document, the FDA stated that its guidance would apply to all types of COVID-19 vaccines in development:

This guidance describes FDA’s current recommendations regarding the data and information needed to support the issuance of an Emergency Use Authorization (EUA) under section 564 of the FD&C Act (21 U.S.C. 360bbb-3) for an

investigational vaccine to prevent COVID-19, including chemistry, manufacturing, and controls information (CMC); nonclinical data and information; and clinical data and information, as well as administrative and regulatory information. In addition, the guidance provides recommendations regarding key information and data that should be submitted to a relevant investigational new drug application (IND) or cross-referenced master file (MF) prior to submission of an EUA request in order to facilitate FDA's complete and timely review of such a submission, including convening the Vaccines and Related Biological Products Advisory Committee (VRBPAC). ***This guidance also discusses FDA's current thinking regarding the circumstances under which the issuance of an EUA for a COVID-19 vaccine would be appropriate***, providing additional context to the discussion regarding EUAs in the guidance for industry entitled "Development and Licensure of Vaccines to Prevent COVID-19" (Ref. 1).

These recommendations are specific to COVID-19 vaccines, which are complex biological products that are intended to be administered to millions of individuals, including healthy people, to prevent disease. These vaccines have the potential for broad use under an EUA. The recommendations in this guidance are not necessarily applicable to drugs and biological products intended for treatment of COVID-19, for which there may be significantly different considerations under the standard set forth in section 564 of the FD&C Act (21 U.S.C. 360bbb-3), reflecting the products' characteristics and anticipated clinical uses.

69. The February 22, 2021 Guidance specifically set forth the statutory requirements needed to be met in order for it to issue an EUA for a COVID-19 vaccine:

Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)) (Ref. 3):

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.

- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA will be made on a case by case basis ***considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.***

FDA acknowledges that an EUA for a COVID-19 vaccine may be requested to allow for the vaccine's rapid and widespread deployment for administration to millions of individuals, including healthy people, potentially following interim results from one or more clinical trials meeting prespecified success criteria described in the analysis plan submitted to FDA. In this scenario, for a COVID-19 vaccine ***for which there is adequate manufacturing information to ensure its quality and consistency***, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks ***based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.***

70. The February 2021 guidance states that vaccine candidate sponsors "contact the Center for Biologics Evaluation and Research's (CBER's) Office of Vaccines Research and Review (OVRR) ***as early in development as possible*** to discuss expectations and considerations for the sponsor's particular vaccine." The FDA also recommended that "vaccine sponsors ***engage in early communication with CBER's Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality to discuss facility issues related to manufacturing*** of the particular vaccine."

71. On May 25, 2021, the FDA updated its COVID-19 vaccine industry guidance in a document entitled "Emergency Use Authorization for Vaccines to Prevent COVID-19" "Guidance for Industry." The title page further stated, "This document supersedes the guidance of the same title issued on February 22, 2021 and October 2020." In the "Background" section of the document, the FDA stated that its guidance would apply to all types of COVID-19 vaccines in development:

This guidance was first developed prior to issuance of an EUA for a COVID-19 vaccine and takes into account the EUAs currently in place for COVID-19 vaccines. ***This guidance describes FDA’s current recommendations regarding the data and information needed to support the issuance of an Emergency Use Authorization (EUA) under section 564 of the FD&C Act (21 U.S.C. 360bbb-3) for an investigational vaccine to prevent COVID-19,*** including chemistry, manufacturing, and controls information (CMC); nonclinical data and information; and clinical data and information, as well as administrative and regulatory information. In addition, the guidance provides recommendations regarding key information and data that should be submitted to a relevant investigational new drug application (IND) or cross-referenced master file (MF) prior to submission of an EUA request in order to facilitate FDA’s complete and timely review of such a submission, including convening the Vaccines and Related Biological Products Advisory Committee (VRBPAC). ***This guidance also discusses FDA’s current thinking regarding the circumstances under which the issuance of an EUA for a COVID-19 vaccine would be appropriate,*** providing additional context to the discussion regarding EUAs in the guidance for industry entitled “Development and Licensure of Vaccines to Prevent COVID-19” (Ref. 1).

These recommendations are specific to COVID-19 vaccines, which are complex biological products that are intended to be administered to millions of individuals, including healthy people, to prevent disease. These vaccines have the potential for broad use under an EUA. The recommendations in this guidance are not necessarily applicable to drugs and biological products intended for treatment of COVID-19, for which there may be significantly different considerations under the standard set forth in section 564 of the FD&C Act (21 U.S.C. 360bbb-3), reflecting the products’ characteristics and anticipated clinical uses.

72. In a section of the May 25, 2021 guidance entitled “PRIORITIZATION OF REQUESTS FOR ISSUANCE OF AN EUA FOR A COVID-19 VACCINE,” it stated:

When FDA assesses investigational COVID-19 vaccines for use under EUA, FDA’s review includes: stringent evaluation of product quality, including a determination that the facilities producing the product meet appropriate standards; evaluation of the conduct of clinical trials; and assessment of trial data integrity. As noted in section IV above, early interaction with the Agency is critical. FDA intends to decline to review and process EUA requests in cases where it is not feasible for the Agency to verify any one of these characteristics. Additionally, given the need to address urgent public health priorities, FDA may need to further prioritize among the EUA requests it receives for COVID-19 vaccine candidates. For the remainder of the current pandemic, FDA may decline to review and process further EUA requests other than those for vaccines whose developers have engaged in an ongoing manner with the Agency during the development of their manufacturing process and clinical trials program as described in this guidance, Emergency Use Authorization for Vaccines to Prevent COVID-19. These COVID-

19 vaccine developers will have had the benefit of FDA feedback early and throughout the development process. Therefore, their EUA requests are more likely to contain the comprehensive data and information needed to demonstrate that issuance of an EUA is appropriate, and the Agency is more likely to be able to confirm the validity of the clinical and manufacturing information submitted in the EUA request.

E. COVID-19 Vaccine Candidates Seeking EUAs

73. By the summer of 2020, OWS had invested billions of dollars towards the development of COVID-19 vaccines and helped coordinate clinical trials throughout the U.S. OWS's developmental vaccine portfolio included candidates from six different companies working towards U.S. EUAs, as described below.

1) Pfizer/BioNTech (BNT162)

74. On July 22, 2020, Pfizer and BioNTech ("Pfizer/BioNTech") announced that the U.S. government, through OWS, placed an initial order for 100 million doses of their mRNA COVID-19 vaccine candidate, BNT162. According to the release, the U.S. government agreed to pay the companies \$1.95 billion for the first 100 million doses (with an option for an additional 500 million doses), following FDA authorization or approval.

75. On November 9, 2020, Pfizer/BioNTech announced the first interim analysis for its BNT162 Phase 3 trial which showed the vaccine to be 90% effective in preventing COVID-19. The release further touted the companies' progress in scaling up vaccine production, stating, "[b]ased on current projections we expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021."

76. On November 20, 2020, Pfizer/BioNTech submitted its EUA request to FDA for BNT162. According to Pfizer/BioNTech, the vaccine demonstrated "a vaccine efficacy rate of 95%, with no serious safety concerns observed to date."

77. On December 10, 2020, the *New England Journal of Medicine* published the results of Pfizer/BioNTech's Phase 3 study for BNT162. The Journal's editors, including Editor-in-Chief, Dr. Eric J. Rubin, an immunologist at the Harvard T.H. Chan School of Public Health—who, as a member of VRBPAC, would also vote later that day on Pfizer/BioNTech's EUA—wrote that Pfizer/BioNTech's vaccine was “a triumph” and that “the trial results are impressive enough to hold up in any conceivable analysis.” He continued:

There is a lot of credit to go around: to the scientists who shared data and who developed the underlying methods and implemented them to create a vaccine, to the clinical trialists who performed high-quality work in the setting of a health emergency, to the thousands of participants who volunteered to take part in the trial, and to the governments that helped create performance standards and a market for the vaccine. ***And all this stands as a template for the many other Covid-19 vaccines currently in development, some of which have already completed their phase 3 trials.***

78. Later that same day, VRBPAC held its meeting to discuss Pfizer/BioNTech's EUA request and to vote whether to recommend the FDA grant the EUA. Ultimately there were more than eight hours of presentations and discussion regarding the vaccine, its efficacy and safety, and related matters. VRBPAC voted to recommend that the FDA issue an EUA for BNT162. The vote was seventeen “yes” and four “no,” with one abstention.

79. The next day, on December 11, 2020, the FDA announced that it had issued its first EUA for a COVID-19 vaccine to be distributed in the U.S. to Pfizer/BioNTech. Its press release stated:

“The FDA's authorization for emergency use of the first COVID-19 vaccine is a significant milestone in battling this devastating pandemic that has affected so many families in the United States and around the world,” said FDA Commissioner Stephen M. Hahn, M.D. ***“Today's action follows an open and transparent review process that included input from independent scientific and public health experts and a thorough evaluation by the agency's career scientists to ensure this vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization.*** The tireless work to develop a new vaccine to prevent this novel, serious, and life-

threatening disease in an expedited timeframe after its emergence is a true testament to scientific innovation and public-private collaboration worldwide.”

The FDA has determined that Pfizer-BioNTech COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19. The data also support that the known and potential benefits outweigh the known and potential risks, supporting the vaccine’s use in millions of people 16 years of age and older, including healthy individuals. ***In making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness and manufacturing quality information.***

80. In discussing its evaluation of the vaccine’s effectiveness data (that is, 95% effective), the FDA emphasized the breadth of the available data and that the majority of participants were in the U.S. target population, stating, “[t]he effectiveness data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who did not have evidence of SARS-CoV-2 infection through seven days after the second dose.” In discussing its evaluation of safety data, the FDA emphasized the breadth of the available data and, again, that the majority of participants were U.S. participants, stating, “[t]he available safety data to support the EUA include 37,586 of the participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants.”

81. The FDA Briefing Document for the Pfizer/BioNTech vaccine, released by VRBPAC on December 10, 2020 (from which the committee recommended FDA EUA approval), described the study’s diverse make up as 49.4% female, 81.9% White, 9.8% African American, 4.4% Asian, and <3% from other racial groups; and 26.2% of participants were Hispanic/Latino.

82. In the Briefing Document’s “Executive Summary,” VRBPAC stated, in describing the overall 95% Phase 3 vaccine efficacy rate, that “[s]ubgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across age groups, genders, racial and ethnic

groups, and participants with medical comorbidities associated with high risk of severe COVID-19.” The Briefing Document included, within the body of the report, an extensive and detailed description and analysis of the vaccine’s efficacy by subgroups, including, by age groups, genders, racial and ethnic groups, and participants with medical comorbidities.

83. The Executive Summary’s description of the safety data also zeroed in on the vaccine’s effect on the diverse population of study participants, stating: “[w]ith the exception of more frequent, generally mild to moderate reactogenicity in participants <55 years of age, the safety profile of BNT162b2 was generally similar across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, and participants with or without evidence of prior SARS-CoV-2 infection at enrollment.”

84. On December 23, 2020, Pfizer/BioNTech announced that the U.S. government ordered 100 million additional doses of BNT162. Then, on February 12, 2021, the companies announced that the U.S. government ordered yet another 100 million doses, bringing the total doses to be supplied to 300 million.

85. On May 6, 2021, it was reported that two new studies showed the Pfizer/BioNTech vaccine to be highly effective against new COVID-19 variants. In one study, the vaccine’s effectiveness against the B.1.1.7 variant ranged from 87% to 89.5%, against the B.1.351 variant it was 72.1% to 75% effective, and, overall, it was 97.4% effective in preventing severe COVID-19.

2) Moderna (mRNA-1273)

86. On April 16, 2020, Moderna announced that it received a \$483 million contract from the U.S. government to accelerate the development of its mRNA COVID-19 vaccine, mRNA-1273. On July 26, 2020, the company announced an additional \$472 million commitment by the government to support the vaccine’s late-stage clinical development, including a 30,000

participant Phase 3 U.S. study. Moderna noted that “[t]he Phase 3 study protocol has been reviewed by the U.S. Food and Drug Administration (FDA) and is aligned to recent FDA guidance on clinical trial design for COVID-19 vaccine studies.”

87. On August 11, 2020, Moderna announced that the U.S. government ordered an initial 100 million doses of mRNA-1273 for \$1.525 billion (which brought the government’s mRNA-1273 commitment to \$2.48 billion).

88. On November 30, 2020, Moderna submitted its EUA request to FDA for mRNA-1273. According to Moderna, mRNA-1273 demonstrated a vaccine efficacy of 94.1%.”

89. On December 11, 2020, Moderna announced that the U.S. government ordered an additional 100 million doses of its vaccine.

90. On December 18, 2020, the FDA announced that it had issued its second EUA for a COVID-19 vaccine to be distributed in the U.S. to Moderna. Its press release emphasized the FDA’s “open and transparent review process” and its application of “rigorous standards.” The release also stressed that it would apply this very same rigorous process and standards to any forthcoming COVID-19 vaccine candidates. The release stated in pertinent part:

“With the availability of two vaccines now for the prevention of COVID-19, the FDA has taken another crucial step in the fight against this global pandemic that is causing vast numbers of hospitalizations and deaths in the United States each day,” said FDA Commissioner Stephen M. Hahn, M.D. ***“Through the FDA’s open and transparent scientific review process, two COVID-19 vaccines have been authorized in an expedited timeframe while adhering to the rigorous standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization that the American people have come to expect from the FDA. These standards and our review process, which are the same we have used in reviewing the first COVID-19 vaccine and intend to use for any other COVID-19 vaccines, included input from independent scientific and public health experts as well as a thorough analysis of the data by the agency’s career staff.”***

The FDA has determined that the Moderna COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the Moderna COVID-19 Vaccine may be effective in preventing

COVID-19. The data also show that the known and potential benefits outweigh the known and potential risks—supporting the company’s request for the vaccine’s use in people 18 years of age and older. ***In making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness, and manufacturing quality information.***

91. The FDA announced that the vaccine was 94.1% effective in preventing COVID-19 among clinical participants. In discussing its evaluation of this effectiveness data, the FDA stated that the EUA was based upon a U.S. study with data of 28,207 participants analyzed. In discussing its evaluation of safety data, the FDA stated, “The available safety data to support the EUA include an analysis of 30,351 participants enrolled in an ongoing randomized, placebo-controlled study conducted in the U.S.”

92. The FDA Briefing Document for the Moderna vaccine, released by VRBPAC on December 17, 2020 (from which the committee recommended FDA EUA approval), described the study’s diverse make up as 47.4% females, 25.3% of individuals ≥ 65 years of age, and 36.5% of participants considered as representing communities of color with 9.7% African American, 4.7% Asian, and <3% from other racial groups; 20% of participants were Hispanic/Latino.

93. In the Briefing Document’s “Executive Summary,” VRBPAC stated, in describing the overall 94% Phase 3 vaccine efficacy rate, that “[s]ubgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.” The Briefing Document included, within the body of the report, an extensive and detailed description and analysis of the vaccine’s efficacy by subgroups, including, by age groups, genders, racial and ethnic groups, and participants with medical comorbidities.

94. The Executive Summary’s description of the safety data also zeroed in on the vaccine’s effect on the diverse population of study participants, stating: “[w]ith the exception of

more frequent, generally mild to moderate reactogenicity in participants <65 years of age, the safety profile of mRNA-1273 was generally similar across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, and participants with or without evidence of prior SARS-CoV-2 infection at enrollment.”

95. On February 11, 2021, Moderna announced that the U.S. government ordered another 100 million doses of its vaccine, bringing the total doses to be supplied to 300 million.

96. On May 5, 2021, Moderna announced interim data from a study of booster shots of its vaccine, showing positive data with respect to certain COVID-19 variants of concern. “As we seek to defeat the ongoing pandemic, we remain committed to being proactive as the virus evolves. We are encouraged by these new data, which reinforce our confidence that our booster strategy should be protective against these newly detected variants. The strong and rapid boost in titers to levels above primary vaccination also clearly demonstrates the ability of mRNA-1273 to induce immune memory,” said Stéphane Bancel, CEO of Moderna.

3) Johnson & Johnson (Ad26.COV2.S)

97. On August 5, 2020, Johnson & Johnson and its subsidiary, Janssen Biotech, Inc. (together, “J&J” or “Janssen”), announced that the U.S. government, through OWS, placed an initial order for 100 million doses of its single dose, viral vector COVID-19 vaccine candidate, Ad26.COV2.S. According to the release, the U.S. government committed more than \$1 billion under the agreement.

98. On February 4, 2021, J&J submitted its EUA request to the FDA for Ad26.COV2.S. According to J&J, Ad26.COV2.S demonstrated a vaccine efficacy of 85% against severe disease.

99. On February 27, 2021, the FDA announced that it had issued its third EUA for a COVID-19 vaccine to be distributed in the U.S. to J&J.

100. Its press release emphasized the FDA's "open and transparent scientific review process" and its application of "rigorous standards." The release stated in pertinent part:

"The authorization of this vaccine expands the availability of vaccines, the best medical prevention method for COVID-19, to help us in the fight against this pandemic, which has claimed over half a million lives in the United States," said Acting FDA Commissioner Janet Woodcock, M.D. ***"The FDA, through our open and transparent scientific review process, has now authorized three COVID-19 vaccines with the urgency called for during this pandemic, using the agency's rigorous standards for safety, effectiveness and manufacturing quality needed to support emergency use authorization."***

The FDA has determined that the Janssen COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the Janssen COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that the vaccine's known and potential benefits outweigh its known and potential risks, supporting the company's request for the vaccine's use in people 18 years of age and older. ***In making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness and manufacturing quality information.***

101. The FDA announced that "the vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination." In discussing its evaluation of this effectiveness and safety data, the FDA stated that the EUA was based upon an analysis a 30,351 participant study conducted in the U.S., South Africa, Mexico, and certain countries in South America.

102. The FDA Briefing Document for the J&J vaccine, released by VRBPAC on February 26, 2021 (from which the committee recommended FDA EUA approval), described the study's diverse make up as 44.5% were female, 20.4% were ≥ 65 years of age, 62.1% white, 17.2% Black or African American, 8.3% American Indian or Alaska Native, 3.5% Asian, 0.3% Native Hawaiian or other Pacific Islander, and 5.4% multiracial; 45.1% of participants were Hispanic/Latino.

103. In the FDA Briefing Document’s “Executive Summary,” VRBPAC disclosed an overall 66.9% Phase 3 vaccine efficacy rate. Moreover, “[i]n general, [vaccine efficacy] among the subgroups (age, comorbidity, race, ethnicity) appears to be similar to the [vaccine efficacy] in the overall study population.” The FDA Briefing Document included, within the body of the report, an extensive and detailed description and analysis of the vaccine’s efficacy by subgroups, including, by age groups, genders, racial and ethnic groups, and participants with medical comorbidities.

104. The FDA Briefing Document’s description of the J&J vaccine safety data also noted:

Subgroup Analyses

With the exception of more frequent, generally mild to moderate reactogenicity in participants 18-59 years of age, there were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. Occurrence of solicited, unsolicited, and serious adverse events in these subgroups were generally consistent with the overall study population.

105. According to a March 16, 2021 report, the J&J Ad26.COVS vaccine demonstrated that it was strongly protective against COVID-19 variants circulating in South Africa and Brazil, where some of its trials were conducted.

106. On July 1, 2021, J&J announced that study data demonstrated that its COVID-19 vaccine “generated strong, persistent activity against the rapidly spreading Delta variant and other highly prevalent SARS-CoV-2 viral variants” and “the durability of the immune response lasted through at least eight months, the length of time evaluated to date.”

4) Novavax (NVX-CoV2373)

107. On February 26, 2020, Novavax announced that it was developing a vaccine to protect against COVID-19. It stated that it “created the COVID-19 vaccine candidates using its

proprietary recombinant protein nanoparticle technology platform to generate antigens derived from the coronavirus spike (S) protein.”

108. To support Novavax’s efforts to develop a COVID-19 vaccine, the Coalition for Epidemic Preparedness Innovations awarded Novavax initial funding of \$4 million on March 10, 2020. And, on April 8, 2020, Novavax announced that its coronavirus vaccine candidate, NVX-CoV2373, which it characterized as “a stable, prefusion protein made using Novavax’s proprietary nanoparticle technology” which incorporated its “Matrix-M™ adjuvant . . . in order to enhance immune response,” would initiate a first-in-human trial in mid-May.

109. On July 7, 2020, Novavax entered into a contract with the U.S. government, through OWS, whereby the government agreed to pay \$1.6 billion to expedite the development of Novavax’s COVID-19 vaccine and, if approved, it would buy 100 million doses.

110. On October 27, 2020, Novavax announced that it expected to begin its Phase 3 trial in the U.S. and Mexico in November 2020, describing the trial as follows:

Novavax’ pivotal Phase 3 clinical trial is being conducted with support from the U.S. Government through Operation Warp Speed. The trial design is harmonized with those of other leading companies, and calls for the enrollment of up to 30,000 participants in the U.S. and Mexico, with proportional representation among diverse populations most vulnerable to COVID-19 distributed across race/ethnicity, age and those living with co-morbidities. The trial protocol will be posted on Novavax’ website upon initiation.

111. On December 28, 2020, Novavax announced the initiation of its Phase 3 study in the U.S. and Mexico, which it described as follows:

Enrollment and Study Population

Information about the trial and how to enroll in PREVENT-19 is available on clinicaltrials.gov under trial identifier NCT04611802 and www.Novavax.com/PREVENT-19.

Novavax plans to recruit, enroll, and study a diverse population with an emphasis on communities and demographic groups most impacted by the disease as well as

to maximize participation of older adults and those living with co-morbid conditions (e.g., obesity, hypertension and diabetes) that place them at higher risk of complications from COVID-19. Enrollment goals are:

- ≥ 25 percent of the study population is intended to be in the 65 years of age or older group
- ≥ 15 percent black/African American
- 10-20 percent LatinX
- 1-2 percent American Indian

“We are encouraged by the data generated to-date on NVX-CoV2373 and are optimistic about our ability to positively build on the body of evidence with this trial,” said Gregory M. Glenn, M.D, president of research and development, Novavax. “We recognize that volunteers considering our trial may have questions about the potential impact on their ability to receive an authorized vaccine when it becomes available to them. We wish to reassure participants that we are working to ensure that their involvement in our trial does not negatively impact their ability to be vaccinated at the appropriate time.”

Many of the trial sites participating in PREVENT-19 are part of the NIAID-supported COVID-19 Prevention Network (CoVPN), which includes existing NIAID-supported clinical research networks with infectious disease expertise and was designed for rapid and thorough evaluation of vaccine candidates and monoclonal antibodies for preventing COVID-19.

“This trial underscores the importance of private/public partnerships in solving the need for globally available vaccines to interrupt the ongoing COVID-19 epidemic,” said Larry Corey, M.D., virologist at the Fred Hutchinson Cancer Research Center and co-leader of the CoVPN.

In the interest of transparency and scientific exchange and to demonstrate the rigor with which the study is being executed, Novavax has posted the Phase 3 trial protocol on its website at [novavax.com/resources](https://www.novavax.com/resources).

112. On February 4, 2021, Novavax announced that it had begun the rolling review process for authorization of NVX-CoV2373 by multiple regulatory agencies. Novavax explained that the “reviews will continue while the [C]ompany completes its pivotal Phase 3 trials in the United Kingdom (U.K.) and United States (U.S.) and through initial authorization for emergency use granted under country-specific regulations.” As part of the rolling review, Novavax explained that it would continue to submit additional information, including clinical and manufacturing data,

to the agencies. That same month, Novavax announced the complete enrollment of PREVENT-19, its pivotal Phase 3 study in the United States and Mexico to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373.

113. Around this time, Novavax indicated that the vaccine's development was on track and that it expected to submit an EUA request to the FDA during Q2 2021. In May 2021, however, Novavax disclosed that due to manufacturing issues, it would likely delay its EUA submission until Q3 2021.

114. On June 14, 2021, Novavax announced the results from its PREVENT-19 Phase 3 clinical trial, which had enrolled 29,960 adult volunteers in the United States and Mexico. NVX-CoV2373 reportedly demonstrated 90.4% efficacy in preventing symptomatic COVID-19 and 100% protection against moderate/severe disease.

5) AstraZeneca (AZD1222)

115. On May 21, 2020, it was reported that the U.S. government, through OWS, placed an initial order with AstraZeneca for 300 million doses of its viral vector COVID-19 vaccine candidate, AZD1222. The U.S. government committed more than \$1.2 billion under the agreement to fund development, production, and delivery of AZD1222, including supporting a Phase 3 clinical trial in the U.S.

116. On August 31, 2020, AstraZeneca announced its Phase 3 U.S. clinical trial to assess AZD1222's safety, efficacy, and immunogenicity. It stated, "[t]rial centers across the [U.S.] are recruiting up to 30,000 adults aged 18 years or over from diverse racial, ethnic and geographic groups who are healthy or have stable underlying medical conditions, including those living with HIV, and who are at increased risk of infection from the SARS-CoV-2 virus."

117. On March 22, 2021, AstraZeneca announced an interim analysis of its U.S. Phase 3 trial for AZD1222, reporting that the vaccine was 79% effective at preventing symptomatic COVID-19 and 100% effective against severe disease. The company stated that, “[v]accine efficacy was consistent across ethnicity and age,” noting that the trial’s diverse participant enrollment including 22% Hispanic, 8% Black/African American, 4% Native American, and 4% Asian. AstraZeneca further announced that it intended to submit its EUA application to the FDA “in the coming weeks.”

118. On May 7, 2021, *The Wall Street Journal* reported that AstraZeneca was weighing seeking full FDA approval for AZD1222 via a BLA, instead of an EUA. According to the article, “[t]he U.S. government, which helped fund AstraZeneca’s vaccine U.S. testing and development, must sign off on any decision to skip an emergency-use application.” It continued, “*[t]he U.S. has ordered so many doses of already-approved shots that there is little urgency in rolling out the AstraZeneca vaccine domestically. That is a big factor in the company’s discussions with U.S. government and FDA officials, the people familiar with the discussions say.*”

119. On July 29, 2021, AstraZeneca announced that its pivot to a BLA request for AZD1222 would delay its FDA application since “[a] BLA is a much bigger submission than the emergency use approval.”

6) Sanofi/GSK (VAT00008)

120. On July 31, 2020, Sanofi and GSK (“Sanofi/GSK”) announced that the U.S. government, through OWS, placed an initial order for 100 million doses of their recombinant protein-based vaccine candidate. According to the release, the U.S. government committed more than \$2.1 billion under the agreement to fund clinical trials and manufacturing scale-up.

121. In September 2020, Sanofi/GSK started Phase 1/2 trials with 441 participants in the United States. In February 2021, Sanofi/GSK started Phase 2 trials with 720 participants in the United States, Honduras, and Panama.

122. On May 27, 2021, Sanofi/GSK announced that they began enrollment in their Phase 3 clinical study which would enroll 35,000 participants in multiple countries, including sites in the U.S., Asia, Africa, and Latin America.

F. COVAXIN: India's Home-Grown COVID-19 Vaccine

123. COVAXIN is a whole-virion inactivated vaccine to prevent COVID-19 infection in humans, developed by an Indian company, Bharat, in collaboration with two Indian government-backed institutes, the Indian Council for Medical Research ("ICMR"), an Indian government funded biomedical research institute, and its subsidiary, the National Institute of Virology ("NIV").

124. COVAXIN's development commenced on May 9, 2020 when NIV announced that it had transferred a strain of COVID-19 to Bharat for the development of a vaccine. By then, however, dozens of vaccine developers around the world had already begun developing COVID-19 vaccines. Indeed, AstraZeneca and Pfizer had already begun Phase 2 trials.

125. In theory, Bharat's vaccine design for COVAXIN, that is, an "inactivated virus," was straightforward. Bharat would inactivate the COVID-19 virus with a chemical called beta propiolactone which jumbles up the genetic code of the virus. While this takes away the virus' ability to infect people, it still leaves the pathogen's outer shell intact. When these shells are injected into the human body, the body mounts an immune response to the proteins on the shell, known as antigens.

126. But despite being an established technology, there are several reasons why producing inactivated virus vaccines is not easy. For example, manufacturing them is challenging, which is one reason why few countries pursued them. To make them, the manufacturer must grow large quantities of the COVID-19 virus and fully inactivate them. And because the COVID-19 virus is dangerous, the live virus must be grown in Biosafety Level 3 (BSL-3) manufacturing facilities, which deploy significant safety measures to prevent viral escape. In contrast, mRNA vaccines (such as Pfizer/BioNTech and Moderna) and adenovirus vector vaccines (such as J&J and AstraZeneca) may be made in more common BSL-1 and BSL-2 facilities.

127. Inactivated virus vaccines have other unique safety issues. First, even though inactivated vaccines are not uncommon, COVAXIN includes an adjuvant, called Algel-IMDG, which reportedly had never been used in a commercial human vaccine before. Second, there is a concern about enhanced-respiratory disease (“ERD”), a phenomenon in which the vaccine causes severe COVID-19 rather than protecting against it. While ERD is a risk with all COVID-19 vaccine platforms, it is more likely with inactivated virus vaccines. Finally, there are serious risks associated with working with a live virus, risks which caused the U.S. to entirely omit the vaccine platform from its Operation Warp Speed.

128. By the summer of 2020, Bharat was facing pressure by the Indian government to quickly roll out COVAXIN, even though it had only been tested on animals and was in the process of being advanced to a Phase 1 human safety study. On July 2, 2020, the ICMR’s Director General reportedly sent a letter to the investigators of Bharat’s planned Phase 1 study stating that COVAXIN development was being monitored at the “topmost level of the government” and that the vaccine would be launched the following month, on August 15, 2020 (India’s Independence

Day). The letter not only implied that Bharat might skip Phase 2 and Phase 3 trials, but it signaled that it was okay to cut corners in the interest of speed.

129. The All India People's Science Network ("AIPSN"), a network of Indian scientists, believed that the letter was calculated to help Prime Minister Narendra Modi talk up the Make-in-India campaign during his yearly Independence Day speech. In response, they wrote, "A desire to grandstand and please the political masters seems to have overtaken science and ethics within ICMR. AIPSN deplores the emerging trend in India of short-circuiting established protocols for trials of [COVID-19] vaccines and treatment drugs."

130. On December 8, 2020, the *Press Trust of India* reported that Bharat had sought accelerated approval from India's drug regulator, the Drug Controller General of India ("DCGI"). Accelerated approval is the Indian equivalent of the FDA's EUA. At the time, the COVAXIN Phase 3 trial (which sought to enroll 25,800 Indian subjects) had just gotten underway with the first participant enrolled on November 11, 2020. Thus, Bharat neither had any efficacy estimate for COVAXIN, nor any adverse event data, given that no study participant had even received a second vaccine.

131. On January 3, 2021, the DCGI granted COVAXIN accelerated approval in India, despite the stark absence of Phase 3 data. An immunologist at the Indian Institute of Science Education and Research called the approval "unconscionable." "Approval was premature and could be dangerous," said former minister Shashi Tharoor.

132. On January 5, 2021, Bharat defended COVAXIN's hasty approval claiming that it could be more effective against new COVID-19 strains but conceding that "[i]t's only a hypothesis right now."

133. The Indian government sought to address concerns that COVAXIN was prematurely approved due to government pressure by describing COVAXIN as only a “back-up vaccine” to be put to use in case of a spurt in infections from potential mutant strains. Nonetheless, the premature approval of COVAXIN led to substantial vaccine hesitancy, with at least one Indian state government, Chhattisgarh, reportedly refusing to use the shot.

134. When Russia similarly approved its Sputnik V COVID-19 vaccine without a Phase 3 trial, scientists around the world claimed it was jeopardizing the lives. American virologist Florian Krammer, who had worked on characterizing the human immune response to COVID-19, tweeted: “Not sure what Russia is up to, but I certainly would not take a vaccine that hasn’t been tested in Phase III. Nobody knows if it’s safe or if it works. They are putting HCWs (healthcare workers) and their population at risk.”

135. In early January 2021, the Indian media began reporting on serious legal and ethical breaches at People’s Hospital, the Bhopal site of Bharat’s Phase 3 trial for COVAXIN. The breaches ranged from luring study participants (by not clearly telling them they were part of a clinical trial, and not a vaccination drive) to not following up with participants to record adverse events during the COVAXIN trial. Although Bharat claimed otherwise, the reports seemed to confirm that many in the trial did not have mobile phones or other means by which they could be contacted concerning the study after receiving a shot, nor had they been contacted by other means.

136. On January 14, 2021, *Express Pharma*, an Indian publication on the pharmaceutical industry, reported on the intense backlash against Bharat for its “gross violations” of various laws and guidelines for its clinical trials of COVAXIN. The article, entitled “Halt Bharat Biotech’s COVAXIN trial in Bhopal: Civil society organisations,” stated in part:

Civil society organisations across the country have raised concerns and demanded an immediate stop of the clinical trial of Bharat Biotech’s COVAXIN at People’s

College of Medical Sciences and Research, Bhopal citing gross violation of clinical trial rules and ethics.

The backlash comes in the aftermath of the death of a male trial participant that came to light recently through the media. Several people who were inducted into the clinical trial have also shared their experiences which indicate that there have been gross violations of laws and guidelines governing clinical trials in India, namely the New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research involving Human Participant, 2017 and the National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic, April 2020 published by the ICMR.

So, on January 10, Bhopal-based civil society group had written a letter to Prime Minister Modi along with Health Minister and other concerned authorities demanding the immediate stop of COVAXIN clinical trial site in Bhopal. It has also requested to form an independent body to conduct an impartial, transparent, thorough, and time-bound investigation to ascertain violations of ethics, protocols and legal requirements about the conduct of the clinical trial. And also suggested that the findings of this enquiry must be put in the public domain. Besides this, it also insisted that the independent body must consist of experts, especially civil society representatives who do not have any conflict of interest or connection with the sponsors (BBIL and ICMR), the site (People's College of Medical Sciences & Research, Bhopal) or the researchers.

Now, 42 civil society organisations from across the country have come together and jointly signed a letter stating, "We are supportive of the demands put up by the Bhopal-based organisations on behalf of the trial participants. We demand an immediate, thorough investigation of the issue at hand from the concerned regulatory and ethics compliance offices to look into gross violations. Suitable action needs to be taken against all individuals and structures that are found to be responsible for ethical violations, negligence and endangering the safety of trial participants including investigators, ethics committee, administrators of People's Hospital and the trial sponsors. The immediate action warranted is that the trial at People's Hospital, Bhopal must be immediately brought to a complete halt. The trial sponsors, [Bharat] and ICMR, must take full responsibility for the serious, unconscionable and unlawful lapses in the Bhopal trial."

They highlight that a clinical trial co-sponsored by ICMR is violating both statutory provisions and ethical guidelines laid down by ICMR for the conduct of clinical trials, and this is alarming.

Dr Sulakshana Nandi, National Joint Convenor, Jan Swasthya Abhiyan, said, "The Bhopal site of COVAXIN clinical trial needs to be blacklisted immediately although we are not against any clinical trial. The only thing we require to have transparency and ethical guidelines need to be followed. Participants rights need to be upheld and clinical trial protocol should be followed."

137. A February 9, 2021 article in *The Quint*, an Indian general news and opinion website, reported that the COVAXIN Phase 3 data was tainted because the Phase 3 protocol for COVAXIN was not followed and Bharat violated other applicable rules. It stated:

Now, a copy of the protocol of the Covaxin phase 3 trial, which *The Quint* has reviewed, shows that People's Hospital also violated this protocol, tainting the integrity of data from the site. Several experts *The Quint* spoke to said such protocol violations, together with already documented violations of the New Drug and Clinical Trial Rules 2019 (NDCT 2019), render the data from the site untrustworthy. This, in turn, will impact [Bharat]'s calculations of the efficacy and safety of Covaxin from all of the 26 trial sites at the end of the study.

* * *

If the ethics body had functioned as it was supposed to, it would have evaluated how widespread the breaches were. Several experts told *The Quint* that if they are indeed as extensive as claimed, data from the Bhopal site cannot be used in final calculations for either safety or efficacy.

138. The documented violations of the COVAXIN Phase 3 study's protocol and other applicable rules included, among others: failure to follow up with participants to document COVID-19 infections as well as "solicited adverse events, unsolicited adverse events, serious adverse events, and the occurrence of so-called Vaccine Associated Enhanced Respiratory Disease (VAERD)"; failure to provide copies of consent forms to participants or even inform some participants that they were participating in a trial; and recruiting vulnerable participants without the legally required checks and balances (such as video recordings of consent and impartial witnesses for illiterate participants).

139. According to Anant Bhan, a bioethics researcher at Yenepoya University in Mangaluru, India, Bharat's instinctive dismissal of the documented study violations was perhaps even more concerning than the violations themselves, since *it called into question how the Phase 3 trial was being conducted at the other 25 trial sites*. The February 9, 2021 *The Quint* article

continued:

A far bigger worry than the violations at People's Hospital, however, is ICMR's and [Bharat]'s blanket denial of them. Not only are these bodies overseeing the 25 other phase 3 trial sites, they are also collecting adverse event data from India's Covid immunisation program, of which Covaxin is a critical part, points out Anant Bhan, a bioethics researcher at Mangaluru's Yenepoya University. "To not acknowledge the problems, at all, is worrisome, because what does that tell us about how they handle potential concerns about data quality from other sites? If we are giving Covaxin on a large scale in clinical trial mode, and if this happens in a controlled trial, what about larger rollouts?" asks Bhan.

140. Also in February 2021, the Brazilian government signed a contract to buy twenty million doses of COVAXIN and, on March 8, 2021, Bharat applied for emergency use in Brazil.

141. On March 3, 2021, Bharat released the Indian Phase 3 COVAXIN interim efficacy data which claimed 81% interim efficacy in preventing COVID-19 in those without prior infection after the second dose.

142. On March 30, 2021, the Brazilian drug regulator, Anvisa, published a report listing a litany of quality problems with Bharat's COVAXIN manufacturing plant. ***The problems included insufficient measures to ensure that the COVID-19 virus was completely killed which was the issue that led to the 1955 Cutter incident.*** As alleged above, the potential for such issues had caused the U.S. Operation Warp Speed to rely exclusively on other vaccine platforms. Other issues identified by Anvisa included failure to ensure that the vaccine was free of microbial contamination and possible variations in COVAXIN's potency from one dose to another. Disturbingly, instead of addressing the specific safety issues raised by Anvisa, Bharat's co-founder again simply dismissed the report, blaming Anvisa's observations on Brazil's nationalism and a desire to keep an Indian vaccine out of the country.

143. On April 21, 2021, Bharat issued a press release announcing a claimed COVAXIN vaccine efficacy of 78% against mild, moderate, and severe COVID-19 and 70% efficacy against

asymptomatic COVID-19 infections. The press release also stated that safety and efficacy data from the trial would be released in June 2021.

144. On July 3, 2021, Bharat issued a press release entitled “Bharat Biotech Concludes Final Analysis for COVAXIN® Efficacy from Phase 3 Clinical Trials,” which claimed that COVAXIN was 77.8% effective against symptomatic COVID-19 and 63.6% effective against asymptomatic infections. The final peer-reviewed data for the Phase 3 trial was published in *The Lancet* on November 11, 2021.

G. Ocugen’s Business: 2013 through 2020

145. Ocugen was founded in 2013 by defendant Musunuri and University of Colorado professor Uday Kompella to develop treatments for various sight-threatening diseases.

146. On April 8, 2019, Ocugen announced that it would become a public company via a reverse merger with a failing biotech microcap, Histogenics Corporation.

147. At the time, Ocugen was attempting to develop a small number of drugs to treat rare and underserved eye diseases, none of which had achieved FDA approval or commercial launch. They were: (i) OCU100, a treatment for retinitis pigmentosa (in preclinical development); (ii) OCU200, a treatment for wet age-related macular degeneration (in preclinical development); (iii) OCU300, a drug candidate for ocular graft versus host disease (in Phase 3 clinical development); (iv) OCU310, for dry eye disease (which was in Phase 3 development, but which “did not meet its co-primary endpoints”); (v) OCU400, for certain inherited retinal diseases (with plans to initiate a Phase 1/2a clinical trial within two years); and (vi) OCU410, a gene therapy for the treatment of dry age-related macular degeneration (in preclinical development).

148. Thus, Ocugen was a “development stage company” with no revenues whatsoever and no products approved for sale. Leading up to the merger, Ocugen primarily funded its

operations through the sale of common stock, warrants, convertible notes, and debt. Specifically, since Ocugen's inception and through March 31, 2019, it has raised an aggregate of \$23.3 million to fund its operations and pay its 13 full-time employees.

149. On September 27, 2019, the merger was completed immediately after Histogenics effected a 1-for-60 reverse stock split, the combined company was renamed "Ocugen, Inc.," and the Company's stock began trading on the NASDAQ under the ticker symbol "OCGN."

150. Investors, however, were not impressed. Ocugen common stock, which closed at \$2.85 per share on September 30, 2019, sank to \$0.266 per share on November 25, 2019.

151. On December 27, 2019, Ocugen was notified by the NASDAQ that for the last thirty consecutive business days the closing bid price for the Company's common stock had been below the minimum \$1.00 per share required for continued listing. The Company was given until June 24, 2020 to regain compliance with the NASDAQ rule.

152. On June 1, 2020, Ocugen announced that it had discontinued the Phase 3 trial of OCU300 based on an interim analysis which indicated the trial was unlikely to meet its co-primary endpoints. As a result, Ocugen would no longer pursue the development of this product candidate.

153. On this news, Ocugen's stock price dropped 26% to close at \$0.23 per share on June 1, 2020. The Company's stock price did not soon recover.

154. On June 15, 2020, Ocugen terminated five of its employees, one-third of the Company's workforce, "as part of its recent shift in focus toward its gene therapy platform and novel biologics program[.]"

155. On July 14, 2020, Ocugen common stock closed at just \$0.196 per share.

156. On September 8, 2020, Ocugen announced that the NASDAQ granted it an additional 180 days to regain compliance with its minimum \$1.00 price per share requirement.

157. In Ocugen's SEC Form 10-Q for Q3 2020, filed on November 6, 2020, the Company provided a "going concern" warning to investors, stating that there was "substantial doubt" that Ocugen would be able to continue its business operations, describing its dire financial situation as follows:

The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, warrants to purchase common stock, the issuance of convertible notes, debt, and grant proceeds. The Company incurred net losses of approximately \$18.0 million and \$32.6 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, the Company had an accumulated deficit of \$69.5 million and cash, cash equivalents and restricted cash totaling \$19.3 million.

The Company has a limited operating history and its prospects are subject to risks, expenses and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research and development efforts for its product candidates, which will require significant funding. If the Company is unable to obtain additional financing in the future or research and development efforts require higher than anticipated capital, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by raising additional capital through public and private placements of equity and/or debt, payments from potential strategic research and development arrangements, sale of assets, and licensing and/or collaboration arrangements with pharmaceutical companies or other institutions. Such financing may not be available at all, or on terms that are favorable to the Company. While management of the Company believes that it has a plan to fund ongoing operations, its plan may not be successfully implemented. ***Failure to generate sufficient cash flows from operations, raise additional capital through one or more financings, or appropriately manage certain discretionary spending could have a material adverse effect on the Company's ability to achieve its intended business objectives.***

As a result of these factors, together with the anticipated increase in spending that will be necessary to continue to develop the Company's product candidates, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued. The condensed consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

158. By late December 2020, Ocugen's share price was still hovering around \$0.30 per share, closing at \$0.294 per share on December 21, 2020.

H. Ocugen Pivots; Misleads Investors Regarding COVAXIN's EUA Pathway

159. On December 22, 2020, on the heels of the FDA approving EUAs for Pfizer/BioNTech and Moderna's COVID-19 vaccines, Ocugen issued a press release entitled "Ocugen and Bharat Biotech to Co-Develop COVAXIN™, a Whole-Virion Inactivated COVID-19 Vaccine, for the [U.S.] Market," announcing that it was making a stunning pivot to bringing another COVID-19 vaccine to the United States. The release stated in relevant part:

Ocugen, Inc., (NASDAQ: OCGN), a leading biopharmaceutical company, and [Bharat], a global leader in vaccine innovation, today announced that the companies have signed a binding letter of intent (LOI) to co-develop Bharat Biotech's COVID-19 vaccine candidate, COVAXIN™, an advanced stage whole-virion inactivated vaccine candidate, for the United States market.

* * *

Per the LOI, Ocugen will have [U.S.] rights to the vaccine candidate and, in collaboration with Bharat Biotech, will be responsible for clinical development, registration, and commercialization for the [U.S.] market. The companies have begun collaborating and will finalize details of the definitive agreement in the next few weeks. This collaboration leverages Ocugen's vaccine expertise, and its R&D and regulatory capabilities in the [U.S.].

In preparation for the development of COVAXIN™ in the [U.S.], Ocugen has assembled a Vaccine Scientific Advisory Board featuring leading academic and industry experts to evaluate the clinical and regulatory path to approval in the [U.S.] market.

* * *

"The development and clinical evaluation of COVAXIN™ marks a significant milestone for vaccinology in India. COVAXIN™ has garnered interest from several countries worldwide for supplies and introduction and we are excited to collaborate with Ocugen to bring it to the [U.S.] market," said Dr. Krishna Ella, Chairman & Managing Director of [Bharat].

160. In response, the price of Ocugen common stock more than doubled from a close of \$0.294 per share on December 21, 2020, to a close of \$0.805 per share on December 22, 2020.

The next day Ocugen stock closed at \$2.60 per share, more than eight times its pre-announcement price.

161. On December 23, 2020, Ocugen disclosed the membership of its Vaccine Scientific Advisory Board, which it said was made up of “leading academic and industry experts” who would “evaluate the clinical and regulatory path to approval in the US market of Bharat Biotech’s COVAXIN™.” According to the release, the advisory board would be made up of defendant Forrest, along with Satish Chandran, David Fajgenbaum, Catherine Pachuk, Harvey Rubin, and Susan Weiss.

162. On January 8, 2021, Ocugen announced that, after more than a year, the Company was now in compliance with NASDAQ listing rules, having maintained a \$1.00 per share minimum bid price as required by the rules.

163. On February 2, 2021, Ocugen announced that it had entered into a definitive agreement with Bharat for the commercialization of COVAXIN in the U.S. via an EUA and, eventually, a BLA. Its press release, which was entitled “Ocugen and Bharat Biotech Announce Execution of Definitive Agreement for the Commercialization of COVAXIN™ in the [U.S.] Market,” stated in pertinent part:

Under the terms of the agreement, Ocugen will have [U.S.] rights to the vaccine candidate and will be responsible for clinical development, regulatory approval (including EUA) and commercialization for the [U.S.] market. [Bharat] will supply initial doses to be used in the [U.S.] upon Ocugen’s receipt of an EUA. In addition, Bharat Biotech will support the technology transfer for manufacturing in the [U.S.]. In consideration for the exclusive license to the [U.S.] market, Ocugen will share the profits from the sale of COVAXIN™ in the [U.S.] market with Bharat Biotech, with Ocugen retaining 45% of the profits.

The collaboration will leverage the vaccine expertise of Ocugen’s leadership team. In preparation for the development of COVAXIN™ in the [U.S.], Ocugen’s Vaccine Scientific Advisory Board and Ocugen management have initiated discussions with the [FDA] and the Biomedical Advanced Research and Development Authority (BARDA) to develop a regulatory path to EUA and,

eventually, [BLA] approval in the [U.S.] market for COVAXIN™. Ocugen is also in active discussions with manufacturers in the [U.S.] to produce a significant number of doses of COVAXIN™ to support its [U.S.] immunization program.

164. The “definitive agreement” was the parties’ Co-Development, Supply, and Commercialization Agreement dated January 31, 2021, which was signed by Bharat and Ocugen (through Musunuri). The agreement, which was filed with the SEC in redacted form, included an exhibit entitled “Initial Development Plan,” which describes Ocugen’s development activities to be carried from January 31, 2021 through December 31, 2021, including “regulatory activities to be conducted by [Ocugen]” and “a projected timeline for such activities or to reach certain clinical milestones in the [U.S.].” The agreement further included a provision for a “Joint Steering Committee” comprised of senior personnel of Ocugen and Bharat, whereby each party would keep the other “reasonably informed of its progress and activities” in connection with the agreement, including overseeing, reviewing, and approving Ocugen’s U.S. regulatory activities (which includes projected timelines therefore).

165. As later recognized by Bharat, the foregoing agreement was in some ways historic since “[n]o vaccine manufactured or developed from India ha[d] ever received EUA or full licensure from [the U.S. FDA].”

166. That Ocugen would initially seek a fast-track EUA for COVAXIN, and not a full-fledged BLA approval, was extremely important to investors since the BLA pathway would likely increase the timeline for U.S. authorization and commercialization by one year or more. Indeed, in connection with Ocugen’s announcement of a planned EUA application, it told analysts that it expected to distribute 100 million doses of COVAXIN in the U.S. during 2021. Consequently, Ocugen’s announcement of the definitive agreement caused its stock price to soar, increasing 80%,

from a close of \$1.81 per share on February 1, 2021 to \$3.26 per share on February 2, 2021, on enormous volume.

167. Shortly thereafter, on February 5, 2021, Ocugen filed with the SEC and posted on its website a slide presentation claiming that the Company was in “pre-EUA discussions with FDA,” it was “[t]arget[ing] 100M Doses/Year Starting 2021,” it “[p]lanned [its] EUA Filing with FDA” in “1H 2021,” COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and that “COVAXIN [is a] Vaccine candidate for the US market with potential for significant revenues this year.” Defendants would repeat these same claims throughout the Class Period.

168. The targeting of 100 million COVAXIN doses sold in the U.S. in 2021 was premised upon a quick FDA EUA approval which would necessarily require the FDA accept Bharat’s Indian Phase 3 data, and not require Ocugen to conduct further U.S. studies. If the FDA required Ocugen to pursue the full BLA route for approval and/or otherwise undertake additional U.S. studies, it would significantly delay any COVAXIN roll out, likely delaying FDA authorization or approval and any associated revenues by a year or more.

169. In response to Ocugen’s claims, the price of the Company’s common stock *tripled*, from a close of \$5.25 per share on Friday, February 5, 2021, to a close of \$15.81 per share on Monday, February 8, 2021, on unusually high volume. The \$15.81 per share closing price was 54 times the \$0.29 per share price just seven weeks earlier, prior to the initial announcement of Ocugen’s collaboration with Bharat.

170. Defendants took advantage of the Company’s surging stock price. During the Q1 2021, the Company sold one million shares of common stock in an at-the-market offering and received net proceeds of \$4.8 million. On February 7, 2021, it sold three million shares of the

Company's common stock in a direct offering and received \$21.2 million in net proceeds. Then, on April 28, 2021, Ocugen announced the closing of a \$100 million direct stock offering to healthcare-focused institutional investors resulting in net proceeds to the Company of \$93.4 million.

171. Throughout the Class Period, Defendants continued to promote Ocugen's stock by assuring investors that they expected to submit an EUA application to the FDA in the first half of 2021, receive approval within weeks thereafter, and generate significant revenues in 2021 by selling up to 200 million doses of COVAXIN.

172. Defendants also sought to address any concerns about their timeline by telling investors that an EUA could be based upon the Indian Phase 3 trials, without the need for time-consuming U.S. trials. For example, on March 15, 2021, Musunuri announced that the FDA was "fine with the way the [Phase 3 Indian study's] interim analysis is being done." On March 31, 2021, Defendants again assured investors that it was unlikely that U.S. trials would be necessary since the Indian data would be "translatable" to the U.S. due to the quality of the studies and the "diversity" of the trial participants. Musunuri later specifically assured investors that Ocugen was "following FDA guidance on EUA[s]" and that the FDA had not said that it wanted any U.S. data prior to allowing the COVAXIN EUA submission to go forward.

173. On May 25, 2021, the FDA revised its COVID-19 vaccine EUA guidance by stating that it would decline to review and process EUA requests in cases where it was not feasible for it to verify and undertake a "stringent evaluation of product quality, including a determination that the facilities producing the product meet appropriate standards; evaluation of the conduct of clinical trials; and assessment of trial data integrity." It further stated that it "may decline to review and process further EUA requests other than those for vaccines whose developers have engaged

in an ongoing manner with the Agency during the development of their manufacturing process and clinical trials program.”

174. Defendants responded the next day, after market close, with a press release reassuring investors that Ocugen was “on track” to submit its EUA. In doing so, defendant Forrest suggested that the revised guidance was inapplicable to Ocugen since the guidance specifically referred to spike protein COVID-19 vaccine candidates, not an inactivated virus vaccine like COVAXIN. Moreover, according to Musunuri, the limitations in the guidance were also inapplicable since Ocugen had “been in discussions with the FDA since late last year.” Not only did the new guidance not “raise[] any concerns,” he said, but it “confirm[ed] that Ocugen continue[d] to meet all criteria for submission of an EUA.”

175. Investors responded positively to Defendants’ reassurances, with the price of Ocugen’s common stock jumping from a close of \$7.66 per share on May 26, 2021, to a close of \$8.71 per share the next day, on unusually high volume.

176. But Defendants’ Class Period statements about Ocugen’s development of COVAXIN for the U.S. market were materially false and misleading, and omitted facts necessary to make their statements not misleading. Defendants were not following the FDA’s guidance on EUAs for COVID-19 vaccines, as they had claimed. The FDA’s industry guidance, and its interpretation thereof, repeatedly stressed the need for studies on the target U.S. population, including a diverse study population including representative numbers of participants who were Hispanic, African American, and other ethnicities. And the FDA repeatedly reiterated that it was strictly following, and would continue to strictly apply and follow, its EUA procedures and guidance. Because Ocugen was not following FDA guidance, it would not receive an EUA for

COVAXIN, and any FDA authorization or approval of the vaccine would be delayed by up to a year, if not more, while U.S. trials would be undertaken.

177. Similarly, the FDA’s revised guidance on May 25, 2021 shut the door on any possible EUA for COVAXIN in the U.S. Among other reasons, because Ocugen failed to engage in an “ongoing manner with the [FDA] during the development of their manufacturing process and clinical trials program,” the FDA would not accept, process or review its EUA application. Rather than conceding this fact, however, Defendants misrepresented the new FDA guidance and doubled down on their unachievable timelines.

I. The Truth Makes Its Way Into the Market

178. On June 10, 2021, prior to market open, the Company issued a press release entitled “Ocugen to pursue a BLA path in the US for its COVID-19 vaccine candidate” in which it stated that it would no longer pursue an EUA for COVAXIN and that additional trials would be necessary. The press release stated:

MALVERN, Pa., June 10, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN) (Company), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today announced that upon recommendation from the [FDA], it will pursue submission of a [BLA] for its COVID-19 vaccine candidate, COVAXIN™. The Company will no longer pursue an [EUA] for COVAXIN™.

The FDA provided feedback to Ocugen regarding the Master File the Company had previously submitted and recommended that Ocugen pursue a BLA submission instead of an EUA application for its vaccine candidate and requested additional information and data. Ocugen is in discussions with the FDA to understand the additional information required to support a BLA submission. The Company anticipates that data from an additional clinical trial will be required to support the submission.

“Although we were close to finalizing our EUA application for submission, we received a recommendation from the FDA to pursue a BLA path. While this will extend our timelines, we are committed to bringing COVAXIN™ to the [U.S.] This differentiated vaccine is a critical tool to include in our national arsenal given its

potential to address the SARS-CoV-2 variants, including the delta variant, and given the unknowns about what will be needed to protect US population in the long term,” said [Musunuri], Chairman of the Board, [CEO], and Co-founder of Ocugen.

Ocugen recently announced that it secured exclusive rights to commercialize COVAXIN™ in Canada and has initiated discussions with Health Canada for regulatory approval. The Company will pursue expedited authorization for COVAXIN™ under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 in Canada.

“In clinical trials to date, the emerging safety profile of COVAXIN™ is supportive of it being generally well tolerated with a good safety profile, with Ministry of Health and Family Welfare of Republic of India reporting no potential thromboembolic events following the administration of over 6.7 million doses of COVAXIN™ in that country,” said [Forrest], Acting [CMO] and member of the vaccine scientific advisory board of Ocugen.

179. On this news, the Company’s share price declined approximately 28%, from a close of \$9.31 per share on June 9, 2021 to \$6.69 per share on June 10, 2021, on exceptionally high volume.

180. Later, on June 10, 2021, analyst Chardan Research lowered its per share price target for Ocugen from \$8 to \$4.50 per share, stating that “we estimate that a BLA submission will occur in early 2022, with potential FDA approval around the end of 2022.” Consequently, the analyst’s updated models showed the first U.S. COVAXIN revenues being delayed until 2023.

181. On June 11, 2021, analyst H.C. Wainwright & Co. also lowered its per share price target for Ocugen, stating in its report that “we now expect Ocugen to commercialize COVAXIN in the U.S. in 4Q22, an approximately one-year delay from previously projected 3Q21.” The report further stated, in part:

On June 10, Ocugen announced plans to file a Biologics Licensing Application (BLA) with the FDA for approval of its COVID-19 vaccine, COVAXIN, rather than filing for an Emergency Use Authorization (EUA) as was previously planned, following recent recommendations from the FDA. Recall that in May, the FDA announced that it may decline to review further Emergency Use Authorization (EUA) applications for COVID-19 vaccines. At that time, we did not anticipate this decision would impact Ocugen’s plans to submit an EUA application, as

management had been in discussions with the agency since late last year. Ocugen plans to meet with the FDA in the near future to determine which additional studies will be needed for this regulatory pathway. Management continues to expect filing the final efficacy data from the Phase 3 trial with the FDA by the end of June. While a [U.S.] pediatric study has already been planned, we anticipate Ocugen may need to conduct an additional safety study in adults in the US prior to BLA submission. Albeit management is yet to finalize the design of the study, we expect recruitment and initiation for this study could take several months, and with a safety time point that may be longer than what is required for EUA submission, we now anticipate approval of COVAXIN during mid-2022, which may extend the projected commercialization out to 4Q22.

J. Post-Class Period Admissions

182. Following the June 9, 2021 report that the FDA had recommended that Ocugen abandon its EUA for COVAXIN, Bharat admitted that this result was inevitable for some time. As reported in a June 11, 2021 article published in *The Hindu*, entitled “Covaxin approval in U.S. may take longer,” Bharat stated:

[W]ith a good herd immunity and significant percentage of the population vaccinated, the pandemic is reducing in the U.S. On the sidelines of this, the [FDA] had earlier communicated that no new EUA would be approved for new COVID-19 vaccines.

183. In a September 27, 2021 article entitled “The Case For Covaxin: Ocugen CEO Shankar Musunuri,” published on *In Vivo – Informa Pharma Intelligence*, defendant Musunuri was interviewed concerning Ocugen’s continuing efforts to receive U.S. approval of COVAXIN. In the interview, Musunuri expressed his frustration with the FDA’s unwavering refusal to deviate from its written EUA industry guidance. He further acknowledged that “[a]ll three vaccines that received authorizations or approvals in the US conducted trials in the US, *that is the precedent.*” Musunuri was asked why, unlike Ocugen, Novavax was still able to pursue an EUA for its vaccine “*despite FDA’s signaling in May that it would stop offering EUAs for COVID-19 vaccines.*” In response, he did not take issue with the interviewer’s characterization of the FDA’s May 25, 2021 revised guidance and candidly admitted that “[t]he difference with the Novavax vaccine is that

they recruited patients in the US for their clinical trials, that's the only missing piece." Musunuri admitted that he was not optimistic that the FDA would change its mind and allow Ocugen to pursue an EUA pathway because *"[t]ypically, you would need a clinical study with a US demographic,"* acknowledging that *"[i]t is important to collect the [U.S.] data from a safety perspective, because different groups may have different reactions."*

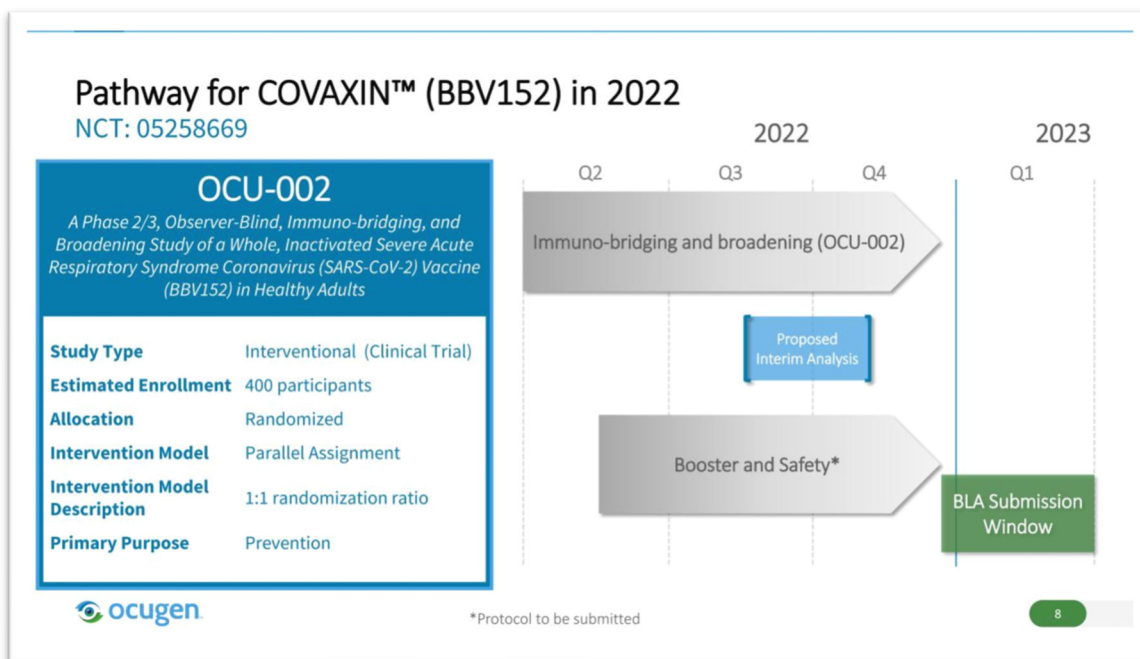
K. Ocugen Pursues FDA BLA Approval for COVAXIN

184. On July 9, 2021, Ocugen filed a presentation with the SEC on Form 8-K which contained a slide confirming its plans with respect to COVAXIN. It stated: "BLA submission to be pursued in the US; discussions ongoing to determine filing pathway."

185. On October 27, 2021, more than four months after Ocugen announced that it would seek a BLA, the Company submitted an Investigational New Drug application (IND) to the FDA for approval to begin its proposed Phase 3 trial for COVAXIN (OCU-002). The study would seek "to establish whether the immune response experienced by participants in a completed Phase 3 efficacy trial in India is similar to that observed in a demographically representative, healthy adult population in the U.S. who either have not been vaccinated for COVID-19 or who already received two doses of an mRNA vaccine at least six months earlier."

186. According to ClinicalTrials.gov, the OCU-002 study, which was subject to two FDA clinical holds, formally commenced on February 20, 2022 and has an estimated primary completion date of September 1, 2023.

187. On March 11, 2022, Ocugen filed a presentation with the SEC on Form 8-K which contained the following slide showing the new timeline for COVAXIN's BLA regulatory pathway:



V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

188. Plaintiff alleges that the statements highlighted in bold and italics within this section were knowingly and materially false and misleading and/or omitted to disclose material information of which Defendants were aware or were extremely reckless in not knowing. As alleged herein, such statements artificially inflated or maintained the price of Ocugen's publicly traded securities and operated as a fraud or deceit on all persons and entities that purchased the securities during the Class Period. Defendants' false and materially misleading statements and omissions include the following.

A. February 2, 2021 Press Release & Guidance

189. On February 2, 2021, prior to market open, Ocugen issued a press release entitled "Ocugen and Bharat Biotech Announce Execution of Definitive Agreement for the Commercialization of COVAXIN™ in the US Market" which stated in pertinent part:

MALVERN, Pa. and HYDERABAD, India, Feb. 02, 2021 (GLOBE NEWSWIRE)
-- Ocugen, Inc., (NASDAQ: OCGN), a biopharmaceutical company focused on

discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to fight COVID-19, and [Bharat], a global leader in vaccine innovation, today announced they have entered into a definitive agreement to co-develop, supply, and commercialize [Bharat]'s COVAXIN™, an advanced stage whole-virion inactivated COVID-19 vaccine candidate, for the United States market.

Under the terms of the agreement, ***Ocugen will have [U.S.] rights to the vaccine candidate and will be responsible for clinical development, regulatory approval (including EUA) and commercialization for the US market.*** [Bharat] will supply initial doses to be used in the US ***upon Ocugen's receipt of an EUA.*** In addition, [Bharat] will support the technology transfer for manufacturing in the [U.S.] In consideration for the exclusive license to the [U.S.] market, Ocugen will share the profits from the sale of COVAXIN™ in the [U.S.] market with [Bharat], with Ocugen retaining 45% of the profits.

The collaboration will leverage the vaccine expertise of Ocugen's leadership team. In preparation for the development of COVAXIN™ in the US, Ocugen's Vaccine Scientific Advisory Board and Ocugen management have initiated discussions with the [FDA] and the Biomedical Advanced Research and Development Authority (BARDA) ***to develop a regulatory path to EUA*** and, eventually, [BLA] approval in the [U.S.] market for COVAXIN™. Ocugen is also in active discussions with manufacturers in the [U.S.] to produce a significant number of doses of COVAXIN™ to support its [U.S.] immunization program.

190. In connection with the foregoing announcement, Ocugen told securities analysts that the Company expected to distribute ***100 million doses of COVAXIN in the U.S. during 2021.*** These securities analysts promptly reported Ocugen's guidance and incorporated it into their financial models. For example, on February 2, 2021, in updating its 2021 financial model for Ocugen to include \$281 million in COVAXIN revenue beginning in Q2 2021, Cantor Fitzgerald mentioned "***the 100 million doses/yr. estimate that Ocugen has cited for U.S. distribution.***" The next day, Roth Capital Partners issued a report setting forth its models showing \$624.65 million in 2021 COVAXIN revenue, which "assume[d] a first batch of ***100M doses delivered in 2021*** at a price point of \$19.50 per dose."

191. The statements referenced in ¶¶ 189-190 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and

timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. Such omissions and failures to disclose rendered the statements made concerning the potential for an EUA for COVAXIN and the expected distribution of 100 million doses in 2021 materially misleading. The statements about pursuing an EUA for COVAXIN and distributing 100 million doses in the U.S. during 2021 communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization. This was untrue. Defendants failed to disclose that, notwithstanding their profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

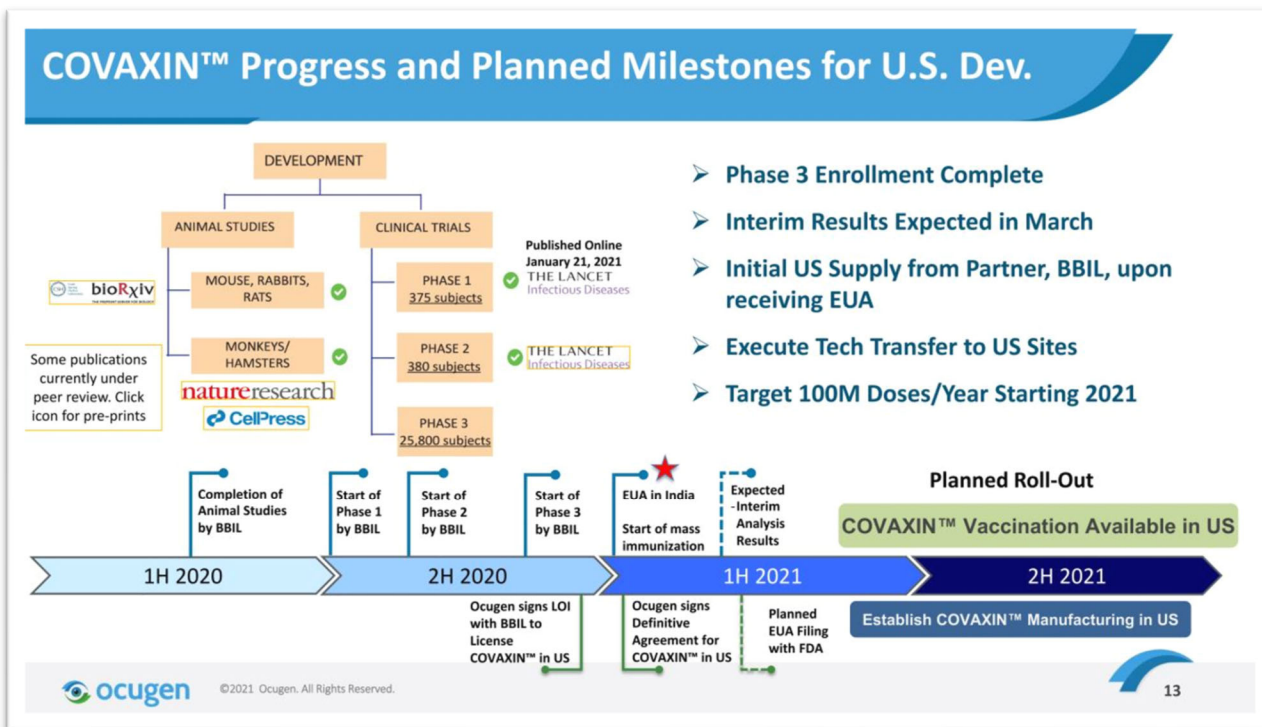
- (i) FDA industry guidance for COVID-19 vaccine EUAs, and the agency's interpretation thereof (together, "Industry Guidance"), required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat's Indian study protocol violations and the FDA's inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen's failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider "the characteristics of the [COVID-19 vaccine] product," coupled with the OWS's decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval

of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and

- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

B. February 5, 2021 SEC Form 8-K & Website Posting

192. On February 5, 2021, after market close, Ocugen filed a slide presentation with the SEC on Form 8-K (signed by Musunuri) entitled “Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19” “Corporate Deck: February 2021” and also posted the same presentation on its website (with a link to the presentation prominently placed on the website’s landing page). In the presentation, Ocugen and Musunuri stated that the Company *was in “pre-EUA discussions with FDA,” it was “[t]arget[ing] 100M Doses/Year Starting 2021,” it “[p]lanned [its] EUA Filing with FDA” in “1H 2021,” COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and that “COVAXIN [is a] Vaccine candidate for the US market with potential for significant revenues this year.”* Ocugen’s presentation included the following slide:



193. The statements referenced in ¶ 192 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. Such omissions and failures to disclose rendered materially misleading the statements made concerning submission of an EUA application for COVAXIN in the first half of 2021 ("1H 2021"), the availability of COVAXIN in the U.S. in 1H 2021, and the significant revenues from the expected distribution of 100 million doses in 2021. The statements about the timing of an EUA application for COVAXIN and the U.S. availability of COVAXIN, and the 100 million doses to be distributed in the U.S. during 2021, communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization. This was untrue. Defendants failed to disclose that, notwithstanding their

profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat's Indian study protocol violations and the FDA's inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen's failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider "the characteristics of the [COVID-19 vaccine] product," coupled with the OWS's decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and
- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

C. March 2, 2021 *The American Bazaar* Article

194. On March 2, 2021, *The American Bazaar*, an online publication covering the Indian American community, published an article entitled "Pennsylvania-based Ocugen selected to market India's Covaxin in US" which included an "exclusive interview" with Musunuri concerning Ocugen's development of COVAXIN. According to the article, Musunuri stated that

Ocugen had “initiated discussions with the FDA and BARDA *to develop the regulatory path for the EUA and eventual full approval in the United States for Covaxin.*” And that it “expect[s] efficacy data early in March *and will proceed full speed ahead at that point towards FDA consideration of EUA for Covaxin in this country.*” He further stated that “*we are aiming for 100 million doses this year.*”

195. Musunuri’s statements referenced in ¶ 194 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to him. Musunuri’s statements communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization. This was untrue. Musunuri failed to disclose that, notwithstanding his profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat’s Indian study protocol violations and the FDA’s inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen’s failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider “the characteristics of the [COVID-19 vaccine] product,” coupled with the OWS’s decision not to

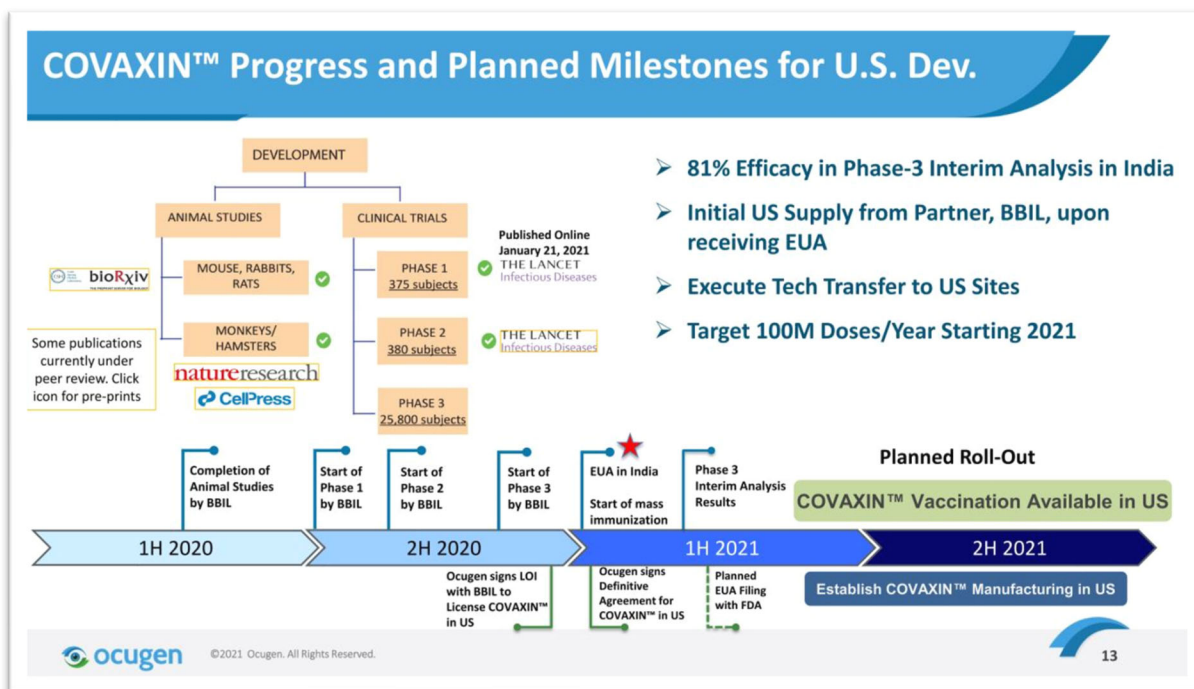
support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;

- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and
- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

D. March 5, 2021 SEC Form 8-K & Website Posting

196. On March 5, 2021, Ocugen filed a slide presentation with the SEC on Form 8-K (signed by Musunuri) entitled “Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19” “Corporate Deck: March 2021” and also posted the same presentation on its website (with a link to the presentation prominently placed on the website’s landing page). In the presentation, Ocugen and Musunuri stated that the Company *was in “pre-EUA discussions with FDA,” it was “[t]arget[ing] 100M Doses/Year Starting 2021,” it “[p]lanned [its] EUA Filing with FDA” in “1H 2021,” COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and that COVAXIN [is a] Vaccine candidate for*

the US market with potential for significant revenues this year.” Ocugen’s presentation included the following slide:



197. The statements referenced in ¶ 196 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. These statements were materially misleading for the same reasons as the same statements made in the February 5, 2021 presentation, as set forth in ¶ 193, above.

E. March 15, 2021 Reuters Article

198. On March 15, 2021, *Reuters* published an article entitled “Ocugen seeks to sell 100 million Indian vaccine doses in U.S. in 2021” which included several statements and quotes from Musunuri, including that Ocugen would seek to sell 100 million doses of COVAXIN in the U.S. in 2021, it aimed to launch COVAXIN in the U.S. during Q2 2021, the Company planned to apply

for an EUA in April, and that the FDA was “fine” with the interim analysis for COVAXIN. The article stated in relevant part:

“[Ocugen] seeks to sell 100 million doses of India’s state-backed COVID-19 vaccine COVAXIN in the United States this year, the U.S. firm’s chief executive [Musunuri] told Reuters on Monday.”

* * *

Musunuri said ***Ocugen aimed to launch the two-dose vaccine in the United States in the second quarter of 2021***, initially with imported shots before beginning production there.

* * *

Musunuri said Ocugen had held initial talks with the [FDA] and ***planned to seek emergency use authorization in April***. . . .

* * *

“They’re fine with the way the interim analysis is being done,” Musunuri said of the FDA, adding that ***Ocugen had “a regulatory path” to take the process forward.***

199. Musunuri’s statements referenced in ¶ 198 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization of, or “regulatory path” for, COVAXIN in the United States and any associated sales and revenues (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to him. Musunuri’s statements communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization. This was untrue. Musunuri failed to disclose that, notwithstanding his profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat's Indian study protocol violations and the FDA's inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen's failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider "the characteristics of the [COVID-19 vaccine] product," coupled with the OWS's decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and
- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

200. Additionally, Musunuri's statement in ¶ 198 above that "*[The FDA is] fine with the way the interim analysis is being done*" is materially misleading because it suggests that the FDA viewed the Phase 3 Indian study to be consistent with its Industry Guidance, which it was not.

F. March 18, 2021 Analyst and Investor Conference Call

201. On March 18, 2021, Ocugen held a conference call with analysts and investors to discuss the Company's business and outlook, including the status of Ocugen's efforts to

commercialize COVAXIN. Ocugen was represented by Musunuri who made prepared statements and took questions from securities analysts. In discussing the planned rollout of COVAXIN to the U.S. market, Musunuri stated that the Company would rely on Indian data to cover the 12 to 16 age group in its forthcoming (April 2021) EUA, while acknowledging that it may need U.S. studies for pediatric and high-risk populations. He further stated that Ocugen would distribute up to **200 million** doses of COVAXIN to the U.S. market in 2021, as set forth below:

The Phase 3 trial, which is being conducted by [Bharat] will result in the final efficacy analysis at the 130 confirmed cases. Currently three EUAs for the other COVID-19 vaccine products in the United States do not authorize use in children under age 16. COVAXIN's Phase 2 results cover adolescents ages 12 plus. There are over 16 million children in the U.S. between ages of 12 and 16, and most of them must attend middle school or high school. ***We are planning to use our existing data to potentially cover this age group in our EUA, offering the potential significant immediate benefit to vaccinate children. We will consider initiating U.S. clinical trials of COVAXIN in addition of patient populations, including pediatric and high-risk studies.***

Ocugen is in active discussions with the FDA to continue ***to develop the regulatory pathway for COVAXIN, vaccine candidate, EUA application. Based on our discussions, we are planning to file the EUA application in April on additional efficacy and safety data from Phase 3 clinical trial.*** We're also in discussions with BARDA, the Biomedical Advanced Research and Development Authority regarding their role in procuring medical counter measures of the strategic national stockpile.

With regard to manufacturing, under our agreement with [Bharat], they will supply the initial doses in the United States ***upon EUA approval.*** We'd already working with an FDA approved local CRO to establish release testing of the product for the U.S. market. ***Overall, we're aiming to make up [to] 200 million doses available this year to support the U.S. COVID-19 immunization program.*** We're in discussions with potential U.S. manufacturers and planning to work with [Bharat] on technology transfer, once the initial doses are supplied.

* * *

We look forward to continuing our momentum in 2021 with the planned U.S. rollout of COVAXIN, as well as filing an IND for OCU400 to move our first gene therapy program into the clinic.

202. In response to an analyst question, Musunuri reiterated that “everybody” at Ocugen “strongly” believed that the EUA application would go forward as previously described, without the need for additional, U.S. based trials (other than for pediatric and/or other high-risk approvals). Musunuri responded to the analyst’s question as follows:

Keay Nakae: Okay, great. If required to do some additional clinical study evaluation in the U.S., or are you currently preparing at least in terms of a planning exercise of trying to line up an activity like that?

[Musunuri]: So Keay actually – *yes, based on the need for this vaccine and under emergency use authorization, I mean our team and advisory board, everybody believes strongly. I think there’s a pretty good chance that we can apply for EUA. However, we always prepare for clinical trials as we outlined, and we are planning to conduct pediatric clinical trials and additional trials in the high-risk and so that we are already planning.*

203. Thereafter, Musunuri reiterated that Ocugen would submit its EUA application in April 2021, based upon the anticipated receipt of Phase 3 data from Bharat:

Swayampakula Ramakanth: Regarding the Phase 3 data and the complete analysis of the Phase 3 data, do you have an idea of when [Bharat] would be able to release that?

[Musunuri]: Yes. RK, we are anticipating the – at the next interim to come out sometime in April and estimate it comes out as the release and *we’re going to get all the information and get ready for a EUA submission. So we’re anticipating that in April.*

204. Musunuri’s statements referenced in ¶¶ 201-203 above were materially false and misleading when made because he failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to him. Such omissions and failures to disclose rendered materially misleading the statements made concerning submission of an EUA application for COVAXIN in April, the expected distribution of 200 million doses in 2021, and that

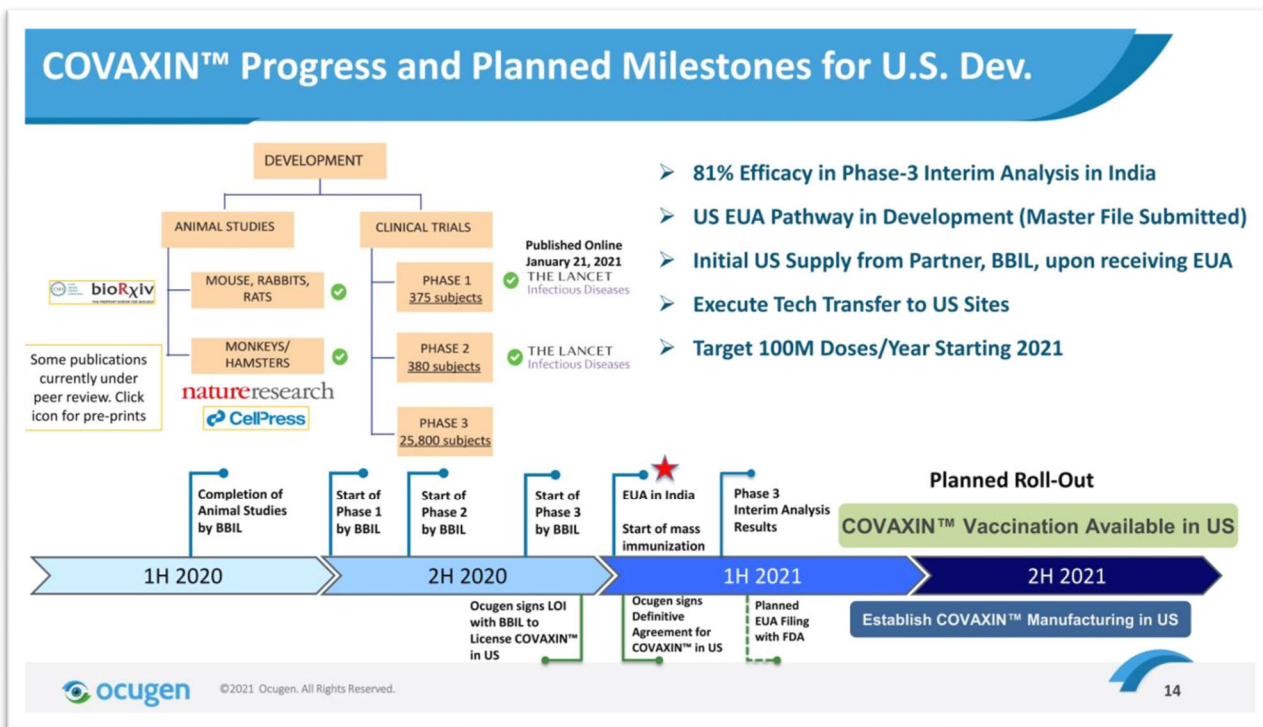
“everybody” at Ocugen “strongly” believed that the EUA application would go forward as previously described. These statements by Musunuri communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization and, if anything, in 2021 Ocugen might now sell 200 million doses instead of 100 million. All of this was untrue. Musunuri failed to disclose that, notwithstanding his profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat’s Indian study protocol violations and the FDA’s inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen’s failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider “the characteristics of the [COVID-19 vaccine] product,” coupled with the OWS’s decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and
- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

205. Additionally, Musunuri's statement in ¶ 201 above that Ocugen would utilize data from the COVAXIN Indian trials for its EUA for ages 12 to 16, and would "consider" U.S. trials for pediatric and other high-risk groups, misleadingly indicated that U.S. trials were unnecessary for the issuance of an EUA by the FDA.

G. March 31, 2021 SEC Form 8-K & Website Posting

206. On March 31, 2021, Ocugen filed a slide presentation with the SEC on Form 8-K (signed by Musunuri) entitled "Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19" "Corporate Deck: March 2021" and also posted the same presentation on its website (with a link to the presentation prominently placed on the website's landing page). In the presentation, Ocugen and Musunuri stated that the Company *was in "pre-EUA discussions with FDA," it was "[t]arget[ing] 100M Doses/Year Starting 2021," it "[p]lanned [its] EUA Filing with FDA" in "1H 2021," COVAXIN shots were expected to be available in the U.S. beginning in "1H 2021," and that "COVAXIN [is a] Vaccine candidate for the [U.S.] market with potential for significant revenues this year."* Ocugen's presentation included the following slide:



207. The statements referenced in ¶ 206 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. These statements were materially misleading for the same reasons as the same statements made in the February 5, 2021 presentation, as set forth in ¶ 193, above.

H. March 31, 2021 Cantor Fitzgerald Virtual Conference

208. On March 31, 2021, Ocugen held a virtual “Fireside Chat” with Cantor Fitzgerald to discuss the development of COVAXIN in the United States. Defendants Musunuri and Forrest spoke on behalf of Ocugen and, as before, claimed the Company fully expected to submit an EUA application for COVAXIN to the FDA in short order. Both indicated that the Indian Phase 3 data

would be translatable to the U.S. due to the quality of the studies and the “diversity” of the trial participants. Musunuri and Forrest responded to some of the moderator’s questions as follows:

Moderator: Could you tell us more about the insights you gained especially when it comes to bringing something safe and applications to the market as rapidly as the COVID-19 vaccine?

Forrest: In fact, in the last 25 years this has been a major improvement in the quality of global clinical trials. We see it across the board with small companies and large. The International Conference on Harmonization, which was mutually set up between the U.S. and Europe and Japan but has now expanded to include other member countries, it sets standards to enable clinical trials that are performed in any given country to meet the standards required by other countries for their approval and that’s what we’re seeing with a quality partner such as [Bharat] in this is that *they’ve made that commitment to do clinical trials to comply with those global standards, those international requirements that will satisfy approvals in countries well beyond just that they’ve done in India especially here in the U.S. So one of those key things is it’s consistency, quality, and a commitment to that and that’s what we’re seeing and that’s why Ocugen is progressed with that partnership.*

* * *

Moderator: Thank you. And then the phase 3 data that was reported earlier this month, could you please speak to the diversity of the subjects in the trial and your take on the data disclosed, and how does this compare to some of the other vaccines in development or proved under EUA? And Dr. Forrest if I could have your thoughts on this first.

Forrest: Absolutely. No the diversity is found in many different ways in vaccine studies. Remarkably vaccines have essentially similar profiles worldwide in the populations today, you see this with vaccines such as Prevena, you see it with rotavirus vaccine such diverse vaccines, now certain select populations for which you may get less of immune response but they still have a degree of protection they wouldn’t otherwise have, *so with vaccines data worldwide for the most part is easily portable and demonstrates uniformity of coverage within the boundaries that we work.* The other thing is India is not a monolithic bloc of homogeneous people *it is a very diverse community it has the same diversity in age, weight, body mass index, underlying conditions and so the data is coming from a very broad cross section of that community both economically as well and socially. And so you’re getting a spread of data in a population that is reassuring that the data you’re seeing is one that can be reliably expected to be translated around the world and I think that’s important.*

* * *

Moderator: And Dr. Musunuri please? You are on mute.

Musunuri: Again, you know ***it is translatable as Bruce stated, the data, again in there is a lot of diversity*** and also if you look at the vaccines in general, they're no different vaccines like you know like even if you take the pediatric vaccine that's not a different vaccine in different parts of the world right? When they conducted clinical trials, I mean, they're the same exact dosing, same exact regimen why is that? ***So, I think in general in the middle of the pandemic I think this can be easily translatable.***

* * *

Moderator: Great and can you please remind our audience about the publicly guided timeline for Covaxin data and do you anticipate running any studies yourself and then can you remind us about the terms of the agreement you have with Bharat on manufacturing and potential sales?

Musunuri: Yes yeah again the publicly guided timelines, I think we kind of updated you know recently that we have filed a master file with FDA. I mean ***if you look at the EUA emergencies authorization vaccines to prevent COVID-19 guidance from FDA, which came out in February***, and one of the paths you know on the way to you EUA you know one could file a master file with a lot of relevant data and before you get the efficacy so that is the first part, it's done. We're in discussions with the agency and understand, you know, hoping to get their feedback ***and the second step is filing the EUA when you have sufficient efficacy from the clinical trial like others have done and also the safety data and there is a certain element of safety has to be collected on the subjects.*** And again, according to our partners they are anticipating that they have two interim looks and one final look. I mean they believe the second interim look data is going to come out this month, next month, which is April, ***and along with that they believe we will be also getting adequate safety data, what we require you know for the submission for the EUA.*** So once again, you know, we're anticipating our partners going to, you know they're working extremely hard, and they're going to get the data efficacy and safety after the second interim look. ***We believe that may be sufficient, you know, to put the data together for the U.S. submission.*** So that's what we're working on. Once again, we still have to wait until they have a second interim look and provide efficacy and adequate safety data for filing.

209. Defendants' statements referenced in ¶ 208 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as*

investors were led to believe), which were known to them. Such omissions and failures to disclose rendered materially misleading the statements made concerning the anticipated submission of an EUA application for COVAXIN and Ocugen’s ability to rely solely on the Indian trials. These statements communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization and that the Indian Phase 3 study was sufficiently “diverse” and “easily translatable” such that it could be “reliably expected” to “satisfy approval[]” requirements around the world, including the FDA’s EUA requirements. In fact, ***Musunuri specifically indicated that Ocugen was following the FDA’s February 2021 EUA guidance.*** All of this was untrue. Defendants failed to disclose that, notwithstanding their profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat’s Indian study protocol violations and the FDA’s inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen’s failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider “the characteristics of the [COVID-19 vaccine] product,” coupled with the OWS’s decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval

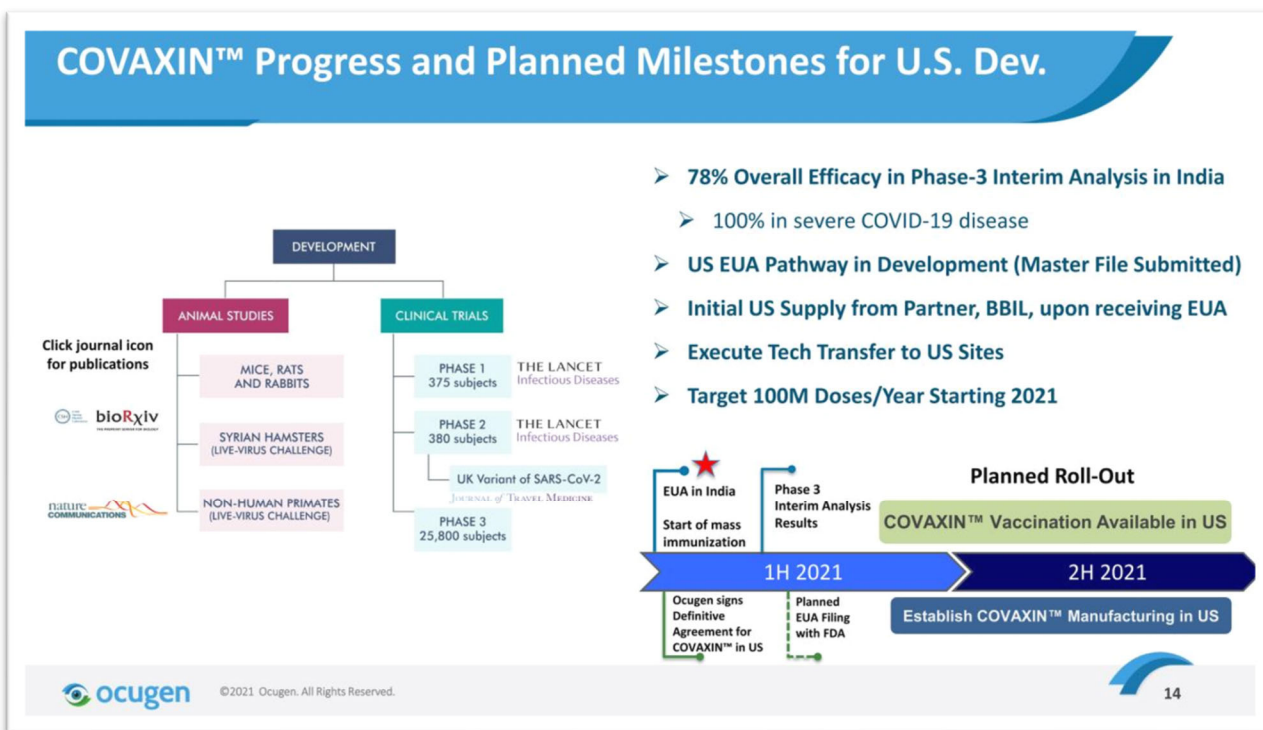
of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and

- (vi) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

I. May 7, 2021 SEC Form 8-K & Website Posting

210. On May 7, 2021, Ocugen filed a slide presentation with the SEC on Form 8-K (signed by Musunuri) entitled “Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19” “Corporate Deck: May 2021” and also posted the same presentation on its website (with a link to the presentation prominently placed on the website’s landing page). In the presentation, Ocugen and Musunuri stated that the Company *was in “pre-EUA discussions with FDA,” it was “[t]arget[ing] 100M Doses/Year Starting 2021,” it “[p]lanned [its] EUA Filing with FDA” in “1H 2021,” COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and that “COVAXIN [is a] Vaccine candidate for*

the [U.S.] market with potential for significant revenues this year.” Ocugen’s presentation included the following slide:



211. The statements referenced in ¶ 210 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. Such omissions and failures to disclose rendered materially misleading the statements made concerning submission of an EUA application for COVAXIN in 1H 2021, the availability of COVAXIN in the U.S. in 1H 2021, and the significant revenues from the expected distribution of 100 million doses in 2021. The statements about the timing of an EUA application for COVAXIN and the U.S. availability of COVAXIN, and the 100 million doses to be distributed in the U.S. during 2021, communicated to investors that—at the time—there were no serious known impediments to an expeditious FDA authorization. This was

untrue. Defendants failed to disclose that, notwithstanding their profoundly optimistic statements, the following then-existing material facts made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable:

- (i) Industry Guidance required a study of a diverse cross-section of the target U.S. population, such that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (ii) Industry Guidance required EUA submissions be supported by clear and compelling data from a well-designed Phase 3 clinical trial, such that Bharat's Indian study protocol violations and the FDA's inability to sufficiently confirm or vet any underlying Indian data ensured that an EUA application for COVAXIN would not be accepted, reviewed, and/or approved prior to the completion of a time-consuming U.S. trial;
- (iii) Industry Guidance encouraged COVID-19 vaccine sponsors to work with the FDA at all stages of vaccine development, such that Ocugen's failure to do so made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (iv) Industry Guidance, which stated that the FDA would consider "the characteristics of the [COVID-19 vaccine] product," coupled with the OWS's decision not to support the development of inactivated virus COVID-19 vaccine candidates due to safety concerns, made FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely;
- (v) Industry Guidance required that there be "adequate manufacturing information to ensure its quality and consistency" before the FDA would consider issuing an EUA for a new vaccine. Bharat's manufacturing information could not reasonably be considered adequate due to the serious manufacturing issues identified in the March 30, 2021 Anvisa report, making FDA authorization of COVAXIN through the abbreviated EUA process extremely unlikely. At the very least, these manufacturing issues made Defendants' timeline for authorization and distribution of COVAXIN in the U.S. unachievable;
- (vi) For the foregoing reasons, an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest; and
- (vii) For the foregoing reasons, whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

J. May 7, 2021 Press Release

212. On May 7, 2021, Defendants issued a press release entitled “Ocugen Provides Business Update and First Quarter 2021 Financial Results” in which they reiterated Ocugen’s steady progress towards EUA approval for COVAXIN in the U.S. The press release stated in pertinent part:

“We continue our dedication to help save lives from COVID-19 by bringing COVAXIN to the U.S. market while simultaneously driving our ophthalmology gene therapy pipeline toward the clinic. We shared compelling second interim analysis results of Bharat Biotech’s Phase 3 clinical trial in India as well as positive data from in-vitro studies regarding COVAXIN’s ability to neutralize emerging variants. ***We continue to make progress toward Emergency Use Authorization for COVAXIN while also considering clinical development in special populations, such as children, as well as booster doses.*** We are delighted to have raised additional capital to fund our ongoing and future operations and to allow us to recruit key talent during this important stage of our growth,” said [Musunuri], Chairman, [CEO], and Co-Founder of Ocugen.

Business Highlights

* * *

•Continued Progress Toward [EUA] — Ocugen is currently in discussions with the [FDA] regarding the development of COVAXIN and has submitted key information and data to date as a Master File for FDA review ***prior to a planned EUA application once additional data is received from [Bharat] from the ongoing Phase 3 clinical trial.*** Ocugen is additionally in discussions with the Biomedical Advanced Research and Development Authority, commonly known as BARDA, regarding the U.S. government’s support of COVAXIN.

213. The statements referenced in ¶ 212 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. Defendants’ statements communicated to investors that—at the time—there were no serious known impediments to an EUA for COVAXIN, and that

while additional studies for “special populations such as children” may be required by the FDA, no additional studies would be necessary for the issuance of an EUA covering healthy adults. This was untrue. Defendants failed to disclose that, notwithstanding their profoundly optimistic statements, the then-existing material facts set forth above at ¶ 211 (i)-(vii) made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable.

K. May 7, 2021 Analyst and Investor Conference Call

214. On May 7, 2021, Ocugen held a conference call with analysts and investors to discuss the Company’s business and outlook, including the status of Ocugen’s efforts to commercialize COVAXIN. Ocugen was represented by Musunuri who made prepared statements and took questions from securities analysts. In response to an analyst question, Musunuri assured investors that Ocugen was “*following FDA guidance on EUA[s]*,” in seeking COVAXIN authorization in the U.S. He further stated that, although a COVID-19 spike in India had delayed some data collection, Ocugen still would complete its EUA application “in the upcoming weeks” and that there was no indication that the FDA would require U.S. studies for EUA approval. As set forth in the conference call transcript, Musunuri responded to the analyst’s question as follows:

Keay Nakae: . . . Couple of questions about the vaccine, [Musunuri], you mentioned some delays due to the activity that’s happening in India. Do you have a sense of when you might be able to complete the EUA filing application?

[Musunuri]: Yes. Keay as we stated, we’re working very hard with our partners at Bharat Biotech and they’d taken longer than anticipated. *We’re planning to still complete the EUA application in the upcoming weeks.*

Keay Nakae: Okay. And in your initial discussions with the FDA, what have they said, if anything about wanting to see vaccine data for U.S. patients before allowing that to move forward?

[Musunuri]: *Not to date.*

215. Musunuri further stated that he anticipated a decision on EUA approval three to four weeks after submission of the application:

Robert LeBoyer: I'm doing well. Thanks. My question has to do with the emergency use application. And when you expect to hear an answer back from the FDA, if positive, what would that mean in terms of rollout and how would it fit with the current vaccination programs?

[Musunuri]: Yes, again, it'll be – we're anticipating it's going to be a similar process to other companies. *After we filed the emergency use authorization application, typically agency takes three to four weeks to make a decision and have a meeting with the [Advisory Committee on Immunization Practices]. And after that, we'd be ready to roll out the vaccine just as other companies are prepared.*

216. Musunuri's statements referenced in ¶¶ 214-215 above were materially false and misleading when made because he failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to him. Musunuri's statements communicated to investors that—at the time—there were no serious known impediments to an EUA for COVAXIN (indeed, it would submit its EUA application “in the upcoming weeks”) and Ocugen was “following FDA guidance on EUA[s].” All of this was untrue. Musunuri failed to disclose that, notwithstanding his profoundly optimistic statements, the then-existing material facts set forth above at ¶ 211 (i)-(vii) made a significant delay in any authorization/approval of COVAXIN by the FDA inevitable.

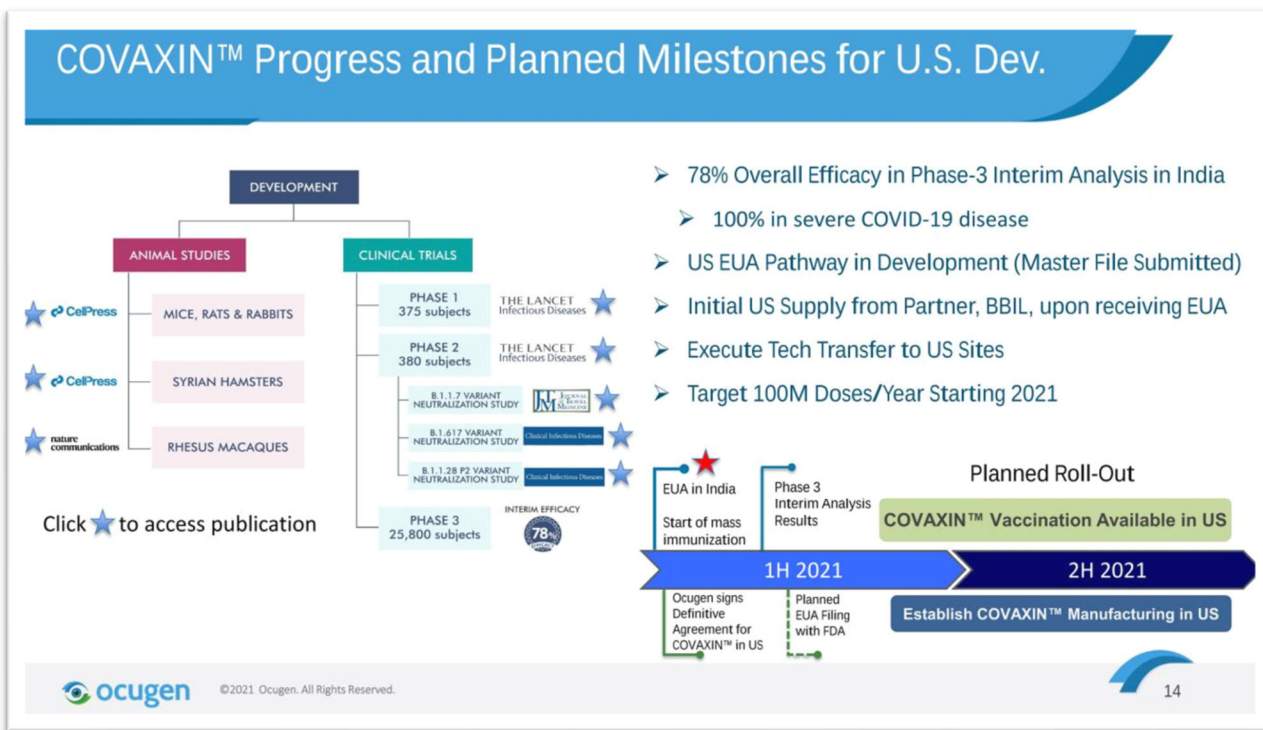
217. Musunuri's statement in ¶ 214 above that Ocugen was “following FDA guidance on EUA[s]” was false because, in fact, Defendants were not following applicable Industry Guidance with respect to EUAs for COVID-19 vaccines.

218. Musunuri's statement in ¶ 214 above that "to date" the FDA purportedly had not said that U.S. trials were necessary was itself misleading since he failed to disclose that such U.S. studies were already required by the FDA in its Industry Guidance.

L. May 19, 2021 SEC Form 8-K & Website Posting

219. On May 19, 2021, Ocugen filed a slide presentation with the SEC on Form 8-K (signed by Musunuri) entitled "Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19" "Corporate Deck: May 2021" and also posted the same presentation on its website (with a link to the presentation prominently placed on the website's landing page). In the presentation, Defendants stated that the Company *was in "pre-EUA discussions with FDA," it was "[t]arget[ing] 100M Doses/Year Starting 2021," it "[p]lanned [its] EUA Filing with FDA" in "1H 2021," COVAXIN shots were expected to be available in the U.S. beginning in "1H 2021," and that "COVAXIN [is a] Vaccine candidate for the US market with potential for significant revenues this year."* The slides containing these statements were substantially similar to those released on May 7, 2021, but included a graphic showing that defendant Forrest had replaced Mohamed Genead as Acting CMO. Ocugen's

presentation included the following slide:



220. The statements referenced in ¶ 219 above were materially false and misleading when made because they failed to disclose adverse facts about the prospects for and timing of any FDA authorization/approval of COVAXIN in the United States (including that *Defendants were not following the FDA's industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants. These statements were materially misleading for the same reasons as the same statements made in the May 7, 2021 presentation, as set forth in ¶ 211, above.

M. May 26, 2021 Press Release

221. On May 25, 2021, the FDA revised its COVID-19 vaccine industry guidance by, among other things, stating that it would decline to review and process EUA requests in cases where it is not feasible for it to verify and undertake a "stringent evaluation of product quality, including a determination that the facilities producing the product meet appropriate standards;

evaluation of the conduct of clinical trials; and assessment of trial data integrity.” It further stated that it “may decline to review and process further EUA requests other than those for vaccines whose developers have engaged in an ongoing manner with the Agency during the development of their manufacturing process and clinical trials program.”

222. On May 26, 2021, after market close, Defendants issued a press release entitled “Ocugen On Track to Submit Emergency Use Authorization Application to U.S. FDA for its COVID-19 Vaccine Candidate, COVAXIN™” which stated that the FDA’s newly-issued guidance would not affect the Company’s ability to receive an EUA for COVAXIN and that the Company was “On Track” to submit the EUA application in June 2021. It stated, in relevant part:

Ocugen On Track to Submit Emergency Use Authorization Application to U.S. FDA for its COVID-19 Vaccine Candidate, COVAXIN™

- Active discussions with FDA related to COVAXIN initiated late last year
- Master file submitted to FDA on March 26, 2021; ***awaiting feedback from FDA***

MALVERN, Pa., May 26, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today ***confirmed its plan to submit its [EUA] application for COVAXIN to the [FDA] in June.***

“Since we have been in discussions with the FDA since late last year, we do not believe that the FDA’s recently revised guidance regarding EUAs raises any concerns about our ability to submit the EUA for COVAXIN as planned, which is currently in process and which we expect to submit to the FDA in June. We believe that the FDA’s new guidance confirms that Ocugen continues to meet all criteria for submission of an EUA. Once the EUA application has been submitted, Ocugen intends to commence pre-biologics license application (BLA) discussions with the FDA,” said [Musunuri], [Chairman], [CEO], and Co-founder of Ocugen.

“FDA’s guidance refers specifically to vaccines based on the spike protein. COVAXIN is a unique yet traditional vaccine using an inactivated version of the whole virus with a novel adjuvant that provides a broadly protective immune response beyond the spike protein, offering potential effectiveness against multiple existing and emerging variants and reducing the possibility of mutant virus escape,” said [Forrest], Acting [CMO] and member of the vaccine scientific advisory board of Ocugen.

223. Defendants’ statements referenced in ¶ 222 above were materially false and misleading when made because they misrepresented and failed to disclose adverse facts about the prospects for a COVAXIN EUA in the United States (including that *Defendants were not following the FDA’s industry guidance for COVID-19 vaccine EUAs as investors were led to believe*), which were known to Defendants or recklessly disregarded by them.

- (a) Musunuri’s statement that Defendants “believe” that the FDA’s new guidance was inapplicable because Ocugen had “been in discussions with the FDA since late last year” was materially misleading because he failed to disclose that the new FDA guidance actually stated that the FDA would prioritize vaccine EUA applications where the developers “have engaged in an ongoing manner with the Agency **during the development of their manufacturing process and clinical trials program**” because such “developers will have had the **benefit of FDA feedback early and throughout the development process**” and that the FDA may decline to review and process all others. Because Ocugen had not engaged in this manner and was admittedly still “awaiting feedback from FDA,” Defendants’ stated “belief” that the guidance was inapplicable was misleading absent the disclosure of the contradictory language in the actual guidance document.
- (b) Musunuri’s statement that Defendants “believe” that the FDA’s new guidance was inapplicable because Ocugen had “been in discussions with the FDA since late last year” was also materially misleading because he failed to disclose that the new FDA guidance stated that early interaction with the FDA in the COVID-19 vaccine development process was “critical” so that the FDA could undertake its “stringent evaluation of product quality, including a determination that the facilities producing the product meet appropriate standards; evaluation of the conduct of clinical trials; and assessment of trial data integrity.” The guidance further stated that as a result the “FDA intends to decline to review and process EUA requests in cases where it is not feasible for the Agency to verify any one of these characteristics.” Because it was “not feasible” for the FDA to undertake its “stringent evaluation” of COVAXIN, as described in the guidance, due to the agency not being involved with the Indian trials, data collection, or vaccine manufacturing, Defendants’ stated “belief” that the guidance was inapplicable was misleading absent the disclosure of the contradictory language in the actual guidance document.
- (c) For these same reasons, it was misleading to say that Defendants believed that the new guidance did not “raise[] any concerns” about the timing of Ocugen’s EUA submission and that they believed the “guidance confirms that Ocugen continues to meet all criteria for submission of an EUA.”
- (d) For these same reasons, and the additional reasons set forth in ¶ 211(i)-(vii) above, it was false and misleading for Defendants to represent that Ocugen was “[o]n

[t]rack” to submit the EUA application for COVAXIN in June 2021. Defendants’ claim was also misleading because, as reported in the Indian media on May 24, 2021, Bharat was in the final stages of negotiations with the FDA for Phase 3 studies of COVAXIN in the U.S.

- (e) Forrest’s statements that the FDA’s updated guidance “refers specifically to vaccines based on the spike protein,” which is unlike COVAXIN’s “unique yet traditional” inactivated virus platform, is materially misleading in that it suggests that the new guidance does not even apply to Ocugen or COVAXIN. Because the guidance by its terms applies to all COVID-19 vaccine candidates, including COVAXIN, Forrest’s statements were materially misleading absent disclosure of the contradictory language in the actual guidance document and absent disclosure that the “spike protein” reference was only contained in an appendix to the guidance.

N. May 2021 Website Posting

224. Defendants’ slide presentation entitled “Our Mission is to Develop Gene Therapies to Cure Blindness Diseases and Develop a Vaccine to fight COVID-19” (“Corporate Deck: May 2021”), which was posted on May 19, 2021 and is described above, remained posted on Ocugen’s website (with a link to the presentation prominently placed on the website’s landing page) after the FDA revised its EUA guidance on May 25, 2021, and it stayed on the website through at least May 30, 2021. In the presentation, Defendants stated that the Company *was in “pre-EUA discussions with FDA,” it was “[t]arget[ing] 100M Doses/Year Starting 2021,” it “[p]lanned [its] EUA [f]iling with FDA” in “1H 2021,” COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and that “COVAXIN [is a] Vaccine candidate for the [U.S.] market with potential for significant revenues this year.”* These statements continued to be materially false and misleading for the same reasons as they were materially misleading on May 19, 2021, as set forth in ¶ 220, above. These statements were also materially false and misleading because the FDA’s May 25, 2021 industry guidance eliminated the EUA pathway for COVID-19 vaccines such as COVAXIN, as set forth in ¶ 223(a)-(e), above.

VI. ADDITIONAL SCIENTER ALLEGATIONS

225. In making their materially false and misleading statements, and in omitting material facts necessary to make their statements not misleading, Defendants acted intentionally and/or with extreme recklessness. In addition to the allegations above which are indicative of Defendants' scienter, the following facts, when considered together with the totality of all circumstances alleged in this Complaint, establish a strong inference of Defendants' scienter.

226. Defendants knew from Industry Guidance—which they assured investors they were following—that the FDA would not authorize COVAXIN or issue an EUA without first requiring a time-consuming U.S. study. The FDA, and those speaking on its behalf, repeatedly emphasized the need for studies of the diverse U.S. target population in its guidance, vaccine candidate briefing documents, meetings, and other statements, as set forth in section IV(D)-(E), above.

227. The Individual Defendants touted their industry experience and regulatory expertise which gave them insight into the FDA's requirements. In its December 22, 2020 press release first announcing its collaboration with Bharat to bring COVAXIN to the U.S., the Company claimed that "[t]his collaboration leverages Ocugen's vaccine expertise, and its R&D and regulatory capabilities in the [U.S.]" Musunuri later claimed that Ocugen's leadership had a "deep history in vaccine development." And Ocugen identified "Vaccine Expertise" as one of its "key competitive strengths," because "[k]ey members of [its] management team and key advisors possess proven expertise and a track record of success in vaccine development and commercialization."

228. Musunuri specifically claimed to have "spent nearly fifteen years at Pfizer, where he gained extensive product launch and life-cycle management experience, playing a key role as Global Operations Team Leader for the most successful launch in vaccine history, Prevnar 13®."

229. Forrest was also an expert in vaccine development, having been appointed a member of Ocugen's Vaccine Scientific Advisory Board, which was tasked with evaluating COVAXIN's "clinical and regulatory path to approval in the [U.S.]" Forrest later became the Company's Acting CMO in mid-May 2021. According to Ocugen's announcement of Forrest's appointment to the vaccine board, "For over 25 years, Dr. Forrest worked as a pharmaceutical industry physician leading the global development of pharmaceuticals, vaccines, and biological drugs. As Senior Vice President at Wyeth Vaccines, Dr. Forrest was responsible for all late phase clinical and pharmaceutical science development activities for vaccines in the Wyeth pipeline, including Prevnar 13®; the meningococcal B vaccine (Trumemba®) and an early investigational *Staphylococcus aureus* vaccine."

230. Additionally, Defendants were each aware of the regulatory requirements for the issuance of an EUA for COVAXIN since no other matter was even remotely as important to Ocugen as was U.S. authorization/approval of COVAXIN. Prior to its deal with Bharat, Ocugen was a failing company, with no material revenue, limited prospects, which was facing delisting, and which had issued a "going concern" warning to investors. With COVAXIN, the Company was suddenly projecting significant revenues in 2021 from the vaccine. One analyst, Cantor Fitzgerald, was modelling 2021 revenue of \$844 million for the year, while another, Roth Capital Partners, estimated 2021 revenue of \$624.7 million. This compares to Ocugen's \$50,620 in total revenue between 2013 and 2020, with no revenue whatsoever between 2014 and 2019.

231. Musunuri was also knowledgeable of the FDA's regulatory requirements for a COVAXIN EUA since he was the driving force behind Ocugen's deal for COVAXIN and a signatory to the Bharat agreement. During the Class Period, he continuously held himself out to the public as knowledgeable of COVAXIN's development, the FDA EUA process, and Industry

Guidance (which he said the Company was following), communications with the FDA, Ocugen's progress towards an EUA submission, and the Company's projections for COVAXIN. In January 2021, Musunuri stated that he was aware of the controversy in India concerning COVAXIN's premature approval and the lack of transparency regarding its clinical trials. Defendant Forrest likewise held himself out as an expert in the EUA process and guidance, and publicly commented on Ocugen's efforts to obtain FDA authorization.

232. That Ocugen's partner and COVAXIN developer, Bharat, conceded that U.S. trials would be necessary prior to FDA authorization is also indicative of Defendants' scienter. On February 17, 2021, soon after Ocugen's COVAXIN deal was finalized, the Co-Founder and Joint Managing Director of Bharat, Mrs. Suchitra Ella, told Bahamian and Jamaican reporters that a U.S. study would be necessary. A February 18, 2021 article in *The Tribune*, a newspaper based in Nassau, Bahamas with a circulation of 7,000 to 10,000, reported as follows:

"We also hope to start trials in the [U.S.] very soon because we have markets where we have entered into commercial agreements with private entities," Ms Ella said. "We will also start doing the bridging studies and trials that have to be done according to the guidelines of their regulatory agencies – whether it is the [U.S.] or Brazil or whichever country is interested to take Covaxin into their markets in the private sector."

"Our partners in the [U.S.] have now applied to the FDA to start the bridging study and the trials that need to be done in the [U.S.] for taking Covaxin to their private markets."

233. Mrs. Ella was aware of the Ocugen's plans as well as U.S. regulatory requirements for COVAXIN due to Bharat's close collaboration with Ocugen and the negotiations leading up to their collaboration agreement, as well as the final January 31, 2021 "Co-Development, Supply, and Commercialization Agreement," which was signed by Bharat and Ocugen (through Musunuri). The agreement included a redacted "Exhibit A" entitled "Initial Development Plan," which purportedly described Ocugen's U.S. development activities to be carried out from January

31, 2021 through December 31, 2021, including “regulatory activities to be conducted by [Ocugen]” and “a projected timeline for such activities or to reach certain clinical milestones in the [U.S.].”

234. On May 24, 2021, it was reported in the Indian press that, according to sources involved in the development of COVAXIN, Bharat was in “advanced” or the “final stages” of negotiations with the U.S. FDA to conduct Phase 3 clinical trials of COVAXIN in the U.S.

235. Following the end of the Class Period, Bharat further confirmed that it was known that the FDA had earlier closed the door on any EUA for COVAXIN. Following the news on June 9, 2021 that Ocugen would pursue a BLA for COVAXIN, on or about June 11, 2021, Bharat admitted that this result was inevitable for some time. It stated:

[W]ith a good herd immunity and significant percentage of the population vaccinated, the pandemic is reducing in the U.S. On the sidelines of this, ***the [FDA] had earlier communicated that no new EUA would be approved for new COVID-19 vaccines.***

236. Defendant Musunuri also later conceded that U.S. trials had always been necessary, despite his wish that the FDA be more flexible. In a September 27, 2021 article entitled “The Case For Covaxin: Ocugen CEO Shankar Musunuri,” published on *In Vivo – Informa Pharma Intelligence*, Musunuri was interviewed concerning Ocugen’s continuing efforts to receive U.S. approval of COVAXIN. In the interview, Musunuri belatedly acknowledged the FDA’s EUA guidance, as well as its “precedent” in requiring U.S. trials prior to granting its three COVID-19 vaccine EUAs (which it did in December 2020 & February 2021). He further expressed his frustration with the FDA’s unwavering refusal to deviate from its written EUA industry guidance:

Q: Last June, Ocugen announced that it would pursue the BLA regulatory pathway, as opposed to an EUA, for Covaxin. ***Is there any possibility, given the magnitude of Delta variant transmission and death in the [U.S.], that the FDA would consider allowing an EUA for Covaxin?***

A: We have been working with the FDA on the regulatory pathway for a BLA, because of the potential for this pandemic to continue for several years. We decided to focus on the long-term strategy and make sure we get the vaccine eventually approved in the [U.S.]. We will continue on that path. However, EUAs are based on unmet medical need and FDA does have a lot of flexibility to grant them. While we are working on the BLA path, there may opportunities, given the Delta variant or other things that could happen in the future, to update the FDA and see what happens. **All three vaccines that received authorizations or approvals in the [U.S.] conducted trials in the [U.S.], that is the precedent. But we are in the middle of a pandemic, and regulators need to be flexible.** We got that flexibility from Health Canada, and our partners are going through the [World Health Organization] approval processes, so hopefully those things may help in the future. We would like to bring this to the [U.S.] market as soon as possible for the benefit of the patients. Our partners at Bharat have also completed a pediatric trial in a two-plus age group. The study was conducted in India, and they are in the final stages of analyzing the data. I think it should come out shortly, in the fall. We're closely watching that and will see what opportunities arise when that data becomes available.

Q: Is there a ballpark timeframe for when you expect clarification from the FDA on clinical requirements for Covaxin, as needed for the BLA?

A: We are hoping the FDA will give us a response quickly: we would like to get started in the fourth quarter. But then two senior people left the agency, one of whom we were interacting with. . . . We are asking for the FDA's help. What bridges do they need? We do have a large data set coming out of India, it is not a small trial, almost 26,000 patients. In India, I think Bharat has administered 50 to 75 million doses. And the numbers are increasing every week, so there is a lot of human experience with Covaxin. ***Of course, certain agencies have certain regulations, and they want you to do certain things. But again, it's a pandemic, and there could be some flexibility. That's why we are waiting.*** As soon as we know how to utilize the data, and see what bridges and other things they need, we are ready. The departure of two senior leaders may have some impact on the timeline, but I'm hoping it won't be too long. It is tough when senior people leave, everything goes into the doldrums.

* * *

Q: Ocugen is pursuing an interim order with Health Canada, the equivalent of an FDA EUA. How do you explain the discrepancy between these two regulators, and why Health Canada, but not FDA, is willing to consider an accelerated, emergency use approval?

A: Based on our interactions, Canada is also looking outward, in the sense of what is going on globally, because remember, these are extraordinary times. And regulators have to make extraordinary decisions. ***Unfortunately, there is no global***

regulatory consensus. In times like this, the [World Health Organization], FDA, [European Medicines Agency] and other large health agencies, including the Indian boards of health, should all be working together. India has a lot of vaccine companies that supply a lot of vaccines, billions of doses every year. Ideally, they would have some consistency, and a treaty would be really helpful for pandemics, and I hope they will do that in the future. But this is the problem, and not just for Ocugen. ***Every company is going through multiple countries, multiple approvals. It is duplicating all the work, why do companies have to go through that? Unfortunately, that is the system. We updated the FDA and Health Canada, and in the case of Health Canada, they were more open to the global experience; they are watching the [World Health Organization] and they agreed to accept a full filing with the data we have. And that was very beneficial. I wish the FDA had the same philosophy, but it does not.***

* * *

Q: Novavax announced its Phase III COVID-19 vaccine trial data around the same as Ocugen, in June and July. Novavax, however, is pursuing an EUA, despite FDA's signaling in May that it would stop offering EUAs for COVID-19 vaccines. What is different about Ocugen's clinical program compared with Novavax?

A: The difference with the Novavax vaccine is that they recruited patients in the [U.S.] for their clinical trials, that's the only missing piece. Novavax is also a spike-based vaccine, so that is not going to solve the problem. Tomorrow, there could be a multivariant emerging. That is why having a differentiated vaccine with broad protection in the toolkit is essential.

* * *

Q: How optimistic or pessimistic are you about the FDA changing its mind, and allowing Ocugen to apply for an EUA as opposed to a BLA pathway?

A: I am not overly optimistic. Typically, you would need a clinical study with a [U.S.] demographic. However, if you take a step back scientifically, and look at what changes from a US clinical study before launching in other countries, the answer is not much. Are you changing any formulation, are you changing any dosage across the globe? ***It is important to collect the data from a safety perspective, because different groups may have different reactions. It is always good to collect data. But in the middle of the pandemic, when history tells you a lot of these inactivated virus vaccines are the same vaccine, including the hepatitis vaccine, that are given to every population across the country, is a [U.S.] study critical?*** Canada and others are saying, it doesn't matter in the middle of the pandemic. So is there a path when you have two-plus pediatric data available? If our partner provides that data before the mRNA vaccines? Will that help? That is another hope, if we get the data ahead of others, then we'll have these serious

discussions with agency. There is an unmet need, and kids are going to school, and parents are really worried about the kids. Is there anything we can do with this? So those are all avenues we're trying to pursue. In fact, we conducted a Harris poll which showed the majority of the vaccine hesitancy people are looking for other options. We believe, based on our poll, that a majority of the vaccine hesitant crowd would take our vaccine, which could be very important for controlling the pandemic. The opportunities are there, but sitting here today, it is tough to read the FDA. But our job is to educate as innovators.

237. Defendants' blatantly deceptive press release in response to the May 25, 2021 revised FDA COVID-19 vaccine EUA guidance is also indicative of their scienter. After the FDA's new guidance was released, Defendants issued a press release assuring investors that Ocugen remained "on track" to submit its EUA. Defendant Forrest suggested that the revised guidance was inapplicable to Ocugen since it specifically referred to COVID-19 vaccine candidates based upon the spike protein, not an inactivated virus vaccine like COVAXIN. However, contrary to Forrest's claim, the new industry guidance, as had earlier FDA EUA guidance, stated that it governed all COVID-19 vaccine candidates. Forrest's purposeful deception is apparent from his calculated citation to a "spike protein" reference buried in an appendix to suggest that the guidance did not apply. And Forrest knew that the revised guidance stated that it superseded the FDA's February 22, 2021 guidance, which Defendants had previously claimed to be following.

238. Musunuri's purposeful deception is evident because he had the new guidance in hand yet claimed it did not "raise[] any concerns" and "confirm[ed] that Ocugen continue[d] to meet all criteria for submission of an EUA." The Individual Defendants' deception is all the more egregious given that their respective comments were not off the cuff but instead they had plenty

of time to review and analyze the FDA's guidance and deliberately craft their respective statements in Ocugen's May 26, 2021 press release.

239. Defendants were motivated, in part, to deceive investors to help Ocugen raise desperately needed capital and avoid delisting. Prior to the Class Period, Ocugen was a failing company. It had only \$50,620 in total revenue between 2013 and 2020, with no revenue whatsoever between 2014 and 2019. In fact, it incurred net losses of approximately \$20.2 million and \$21.8 million in 2019 and 2020, alone. Consequently, from Ocugen's inception in 2013 through December 31, 2020, it was compelled to raise about \$90 million to fund its operations, primarily through the sale of common stock, warrants, convertible notes, and debt. However, by the end of 2020, issuance of new stock became much less appealing as Ocugen's share price hovered around just \$0.30 per share. Indeed, beginning in December 2019 and continuing through the end of 2020, Ocugen faced delisting by the NASDAQ for failure to meet the exchange's minimum \$1.00 per share trading price.

240. Making matters worse, on June 1, 2020, Ocugen abandoned the development of OCU300, a supposedly promising product candidate, which led to the Company terminating one-third of its workforce. Included in Ocugen's reduction in force were two of four or its most highly compensated executive officers, Daniel Jorgensen (its CMO) and Rasappa Arumugham (its Chief Scientific Officer). Afterwards, only Musunuri and Chief Financial Officer, Sanjay Subramanian, remained.

241. Then, in Ocugen's SEC Form 10-Q for Q3 2020, filed on November 6, 2020, the Company provided a "going concern" warning to investors, stating that there was "substantial doubt" that Ocugen would be able to continue its business operations. Thus, Ocugen needed to raise funds in order to survive.

242. Ocugen's stunning pivot from seven years of seeking treatments for eye disorders to—seemingly out of nowhere—seeking to bring another COVID-19 vaccine to the U.S. market, served to address these issues. It allowed the Company to quickly meet the NASDAQ minimum bid requirements and, at the same time, raise additional capital to fund operations.

243. Defendants wasted no time in taking advantage of the hype surrounding their announcement that Ocugen would be pursuing a U.S. EUA for COVAXIN. During the first quarter of 2021, the Company sold one million shares of common stock in an at-the-market offering and received net proceeds of \$4.8 million.

244. On February 7, 2021, immediately after the Company announced that it was targeting 100 million doses of COVAXIN sold in the U.S. for 2021, Ocugen sold three million shares of the Company's common stock in a direct offering and received \$21.2 million in net proceeds. Then, on April 28, 2021, after Ocugen increased its 2021 U.S. COVAXIN target to up to 200 million doses, the Company announced the closing of a \$100 million direct stock offering to healthcare-focused institutional investors resulting in net proceeds to the Company of \$93.4 million. Ocugen had raised more capital in four months than it had in its previous seven years of existence.

245. Defendants were also motivated to push an overly aggressive and unachievable timeline, which had COVAXIN receiving an EUA in the first half of 2021, due to a rapidly closing window of opportunity with respect to new COVID-19 vaccines in the U.S. The need for additional COVID-19 vaccines in the U.S.—and the investor enthusiasm that accompanies such demand—had decreased since the FDA issued EUAs to Pfizer/BioNTech (December 11, 2020), Moderna (December 18, 2020), and J&J (February 27, 2021). By the start of the Class Period, the U.S. government had already ordered millions of doses of COVID-19 vaccines including 200

million doses of Pfizer/BioNTech (which increased to 300 million on February 11, 2021), 200 million of Moderna (which also increased to 300 million on February 11, 2021), and 100 million doses of J&J. It also had already pre-ordered, pending FDA authorization, 300 million doses of AstraZeneca and 100 million each of Novavax and Sanofi.

246. Ocugen was also competing against other vaccine candidates seeking EUAs since the authorization of a fourth or even fifth COVID-19 vaccine in the U.S. would further diminish its prospects and its ability to prop up its stock price and raise capital. Therefore, a truncated (yet, unachievable) timeline was critical to Defendants' scheme. On February 3, 2021, it was reported that Novavax was on track for Phase 3 results in spring 2021, with FDA authorization as soon as April 2021. AstraZeneca had a similar timeline for its EUA application stating on March 22, 2021 that it intended to submit its Phase 3 data and seek an EUA "in the coming weeks."

247. Similarly, as time went on, more Americans would be immune from COVID-19 due to vaccination and infection. This too would erode investor interest over time. While Ocugen tried to spin COVAXIN as a unique vaccine which could potentially serve as insurance against emerging COVID-19 variants, the vaccines that were already available in the U.S. were proving to be effective against such variants.

248. For these reasons, Defendants were highly motivated to promote a timeline with an EUA for COVAXIN being submitted and approved as early as possible after receiving Bharat's Phase 3 data (*i.e.*, first in April then in June 2021) even though—unlike Novavax and AstraZeneca—Ocugen would not have Phase 3 data from a U.S. study. Given the other vaccines in OWS's pipeline, the hundreds of millions of doses already purchased by the U.S. and the decreasing need for vaccines, had Defendants provided a more realistic timeline of late 2022 or,

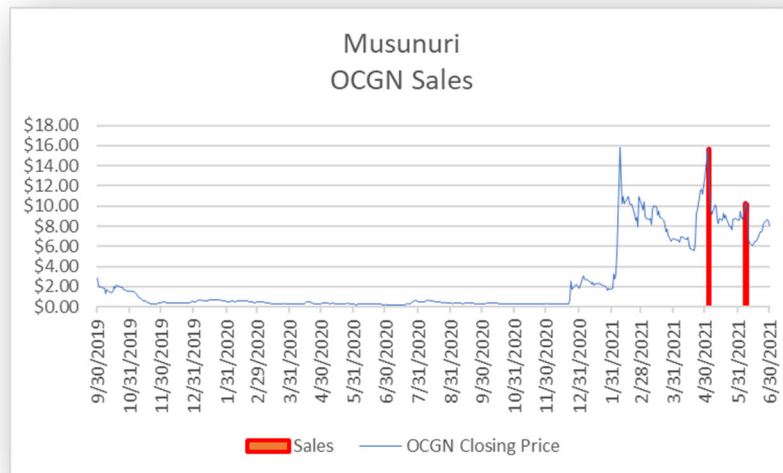
more likely, 2023 for COVAXIN approval, the opportunity would have passed, and they would never have been able to generate the investor excitement and raise the capital that they did.

249. Defendant Musunuri was also motivated to deceive investors to sell his personally held Ocugen shares at inflated prices. During the Class Period, Musunuri reported making the following sales of Ocugen common stock:

Date	Shares Sold	Reported Price/Share	Proceeds
5/3/21	195,809	\$14.24	\$2,788,320
6/7/21	7,758	\$10.94	\$84,872
6/8/21	22,800	\$10.98	\$250,344
<i>TOTAL</i>	<i>226,367</i>		<i>\$3,123,536</i>

250. The foregoing sales were highly unusual and were Musunuri's *first sales of Ocugen stock ever*. At the time Ocugen common stock began trading on the NASDAQ in September 2019, Musunuri had been with the Company for about six years, yet he never sold a single share of Ocugen stock until May 3, 2021.

251. Musunuri's timing was striking, as he realized nearly \$2.8 million in proceeds in a trade at the top of the market, as shown in the following chart illustrating his sales (which are individually listed in above) from the time OCGN began trading on the NASDAQ through the end of the Class Period:



252. Musunuri’s compensation agreement and unusual bonus structure are also probative of his scienter. For 2021, Musunuri received \$8,141,351 in compensation from Ocugen and, a year earlier in 2020, Musunuri’s compensation was \$1,552,178. Because, as of November 2020, there was “substantial doubt” that the Company would continue operating as a going concern for the next year, Musunuri faced an immediate and substantial risk of losing his lucrative executive position.

253. Even more revealing, however, was the unusual bonus plan implemented by Ocugen in March 2021. As part of Ocugen’s executive compensation plan, the Company would award an annual cash bonus to Musunuri based upon achievement of certain pre-determined performance metrics. For 2021, Musunuri could earn a cash award of 50% of his \$500,000 base salary. Also, in April 2021, Ocugen granted performance-based stock options to Musunuri which would only vest upon achievement of certain pre-determined performance metrics.

254. But, in March 2021, the Board of Directors scrapped its 2021 cash bonus framework and revised its performance metrics to focus on Ocugen’s development of COVAXIN. One of these newly-issued 2021 performance metrics for both Musunuri’s cash and option incentive bonuses was “File EUA with FDA for COVAXIN . . . [b]y the end of 2021.”

255. Notably, the applicable milestone was not to *obtain* an EUA for COVAXIN, despite the fact that by this time Defendants—and Musunuri in particular—were telling investors that: (i) the Company was “[t]arget[ing] 100M Doses/Year Starting 2021,” (ii) it “[p]lanned [its] EUA Filing with FDA” in “1H 2021,” (iii) COVAXIN shots were expected to be available in the U.S. beginning in “1H 2021,” and (iv) “COVAXIN [is a] Vaccine candidate for the US market with potential for significant revenues this year.” In March 2021, at the very time the Board of Directors picked this milestone and before it awarded the additional options (in April), Ocugen was telling investors “Ocugen had held initial talks with the U.S. Food and Drug Administration ***and planned to seek emergency use authorization in April.***”

256. Indeed, the purported purpose of the Board of Directors’ additional award of the performance-based stock options to Musunuri in April 2021 was “to reinforce the sense of urgency of our COVAXIN program timeline and deliverables.” Ocugen’s timeline (at least the publicly-disclosed one) involved an EUA for COVAXIN and “significant revenues” in 2021. That the performance-based bonuses were only contingent upon the submission of an EUA application in 2021 supports an inference that Ocugen and the Musunuri knew that an EUA in 2021 was, at best, extremely unlikely, if not impossible. It also suggests why Defendants would continue to claim their EUA submission was “on track” on May 26, 2021, even after the FDA made clear that it would not review and process EUA requests such as the one contemplated by Ocugen. Once an EUA application was filed with the FDA, Musunuri would have earned his bonuses notwithstanding that the FDA already indicated it would be promptly rejected.

257. Musunuri’s past practice of monetizing opportunities relating to COVID-19 through overselling and alleged deception is also probative of his scienter with respect to COVAXIN. COVAXIN was not Musunuri’s first foray into the FDA’s EUA process in connection

with the pandemic. In April 2020, Ocugen entered into a collaboration agreement with Pennsylvania-based ADVAITE, Inc. to assist with its development of a COVID-19 testing kit. Under the agreement, Ocugen was providing “certain production, research and development, technical, regulatory, and quality support services to Advaita in connection with the development and commercialization of the COVID-19 Test.”

258. ADVAITE was purportedly run by Musunuri’s son, Karthik Musunuri (“Karthik”), who co-founded the company in 2017 while he was completing his undergraduate pharmaceutical marketing degree. Like Ocugen, ADVAITE focused on ocular disorders and diseases, describing itself as “a clinical-stage biopharmaceutical company that is developing innovative therapeutic, diagnostic and healthcare solutions to treat ocular surface disorders.” In 2020, ADVAITE hired Vinny Musunuri, another Musunuri son, as manager of corporate strategy. Vinny, who was a sophomore undergrad at University of Southern California at the time, had previously been an intern for Ocugen and for Pennsylvania State Senator Andrew Dinniman.

259. Once the COVID-19 pandemic hit, however, ADVAITE quickly pivoted to an entirely new business, COVID-19 test kits. In April 2020, Senator Dinniman connected ADVAITE with Chester County, Pennsylvania officials for the sale of testing kits. Senator Dinniman later recounted that defendant Musunuri, who had contributed to his campaign committee over the years, was closely involved in ADVAITE’s efforts. “Anything Advaita was doing, [defendant Musunuri] was involved,” he reportedly said.

260. ADVAITE’s unusual pivot paid off. Chester County quickly contracted to purchase \$20 million in tests from the company. ADVAITE’s April 20, 2020 quotation and its invoices for Chester County’s purchase listed ADVAITE’s address as 482 Byers Road, Chester Springs, PA 19425, which is defendant Musunuri’s home address.

261. At the time of the purchase, Renee Cassidy, Chester County's public health physician, reportedly said that "she found it odd that county officials were so eager to purchase tests from [ADVAITE], given the firm's limited track record." Ultimately, Ms. Cassidy's concerns proved prescient. The COVID-19 tests sold by ADVAITE allegedly did not work and, in January 2021, Chester County sued Karthik and ADVAITE for return of \$11 million.

262. ADVAITE allegedly misled the County about another significant matter. According to Chester County's lawsuit, *County of Chester v. Advaita, Inc., et al.*, No. 2021-00374-CT (Pa. C.P. Chester Cnty.), the FDA began issuing EUAs for COVID-19 tests on March 16, 2020. A COVID-19 test with an EUA could be administered by a range of medical professionals who could get real time results in 15 to 30 minutes. In contrast, without an EUA, the test could only be administered by certain qualified medical professionals who would need to verify the results in a clinical laboratory, thereby taking a much longer time and costing additional money. For this reason, Chester County allegedly advised ADVAITE repeatedly that an EUA was material to any purchase by the County.

263. According to the lawsuit, Karthik and ADVAITE repeatedly assured Chester County that an EUA from the FDA was imminent. According to the complaint, on March 24, 2020, Karthik provided Chester County with copies of communications with the FDA regarding the test, and on April 6, 2020, ADVAITE provided a PowerPoint presentation seeking support for the contract which stated "EUA Undergoing Review for Final Approval" and "Acknowledgment and authorization for distribution from FDA received." But on April 14, 2020, Karthik contradicted the foregoing in an email, stating "[w]e actually submitted the EUA today."

264. On April 22, 2020, responding to the County's concerns about the lack of an EUA, Karthik claimed that ADVAITE was "talking with the FDA daily and the most we have seen

turnarounds was 2 weeks post [EUA] submission, and we are hopeful for them to complete their review by then.” According to the complaint, “Chester County regularly and continually raised the issue regarding EUA status to [Karthik] and other [ADVAITE] personnel and received repeated assurance the EUA was coming soon.” On May 28, 2020, Chester County allegedly informed ADVAITE that it would not make any more payments, in part, because ADVAITE had still not received an EUA.

265. ADVAITE’s COVID-19 test did not receive an EUA until nearly eight months later, on January 11, 2021.

VII. LOSS CAUSATION/ECONOMIC LOSS

266. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market, made materially false and misleading statements, and omitted to state material facts necessary in order to make their statements made not misleading, including withholding facts concerning Ocugen’s failure to follow FDA guidance, the regulatory pathway to COVAXIN’s U.S. authorization, the timeline therefore, and the associated U.S. sales. By artificially inflating and manipulating the price of Ocugen securities, Defendants deceived Plaintiff and the Class and caused them losses when the truth was revealed. When Defendants’ prior misrepresentations, omissions, and fraudulent conduct became apparent to the market, it caused Ocugen’s stock price to fall precipitously as the prior artificial inflation left the stock price. As a result of their purchases of Ocugen securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

267. On June 10, 2021, before the markets opened, Ocugen issued a press release announcing that it would pursue a BLA for COVAXIN instead of the previously announced EUA, which would necessarily result in extended timelines for any FDA approval. It further disclosed that the FDA had requested additional information and data, that the FDA recommended the BLA

submission path after reviewing Ocugen's Master File, and that the Company anticipated that it would need to run additional clinical trials.

268. Following this news, Ocugen's common stock price dropped from a \$9.31 per share close on June 9, 2021, to close at \$6.69 per share on June 10, 2021—a single-day decrease of 28%. With an abnormally high 143.5 million shares traded, this resulted in a loss of market capitalization exceeding \$500 million. Financial analysts at Cantor Fitzgerald reduced their price target for Ocugen from \$11 per share to \$4 per share, noting that the BLA timeline would be dependent on the studies required. Chardan Research cut its price target from \$8 per share to \$4.50 per share, stating “[f]or now we estimate that a BLA submission will occur in early 2022, with potential FDA approval around the end of 2022.”

269. The decline in the price of Ocugen securities after the corrective disclosures came to light was a direct result of the nature and extent of Defendants' fraudulent misrepresentations and omissions being revealed to investors and the market and were a substantial cause of the decline. The timing and magnitude of the price decline that Ocugen securities experienced compared to those of its peers and the overall market negate any inference that the loss suffered by Plaintiff and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' deceptive conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Ocugen securities and the subsequent significant decline in the value of Ocugen securities when Defendants' prior misrepresentations, omissions, and other fraudulent conduct were revealed.

VIII. PRESUMPTION OF RELIANCE

270. The market for Ocugen securities was open, well-developed, and efficient at all relevant times. As a result of the Defendants' materially false or misleading statements and

material omissions, the Company's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying on the integrity of the market price of such securities and on publicly available market information relating to Ocugen. The Plaintiff and Class members have been damaged thereby.

271. During the Class Period, the artificial inflation of the value of Ocugen securities was caused by the material misrepresentations and omissions alleged in this Complaint, thereby causing the damages sustained by Plaintiff and other Class members. As alleged herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Ocugen's development of COVAXIN for the U.S. market and the prospects for and timing of any FDA authorization of the vaccine, causing the price of the Company's securities to be artificially inflated at all relevant times. When the truth was disclosed, it drove down the value of the Company's securities, causing Plaintiff and other Class members that had purchased the securities at artificially inflated prices to be damaged as a result.

272. At all relevant times, the market for Ocugen securities was an efficient market for the following reasons, among others:

- (a) Ocugen's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient, national stock market;
- (b) as a regulated issuer, Ocugen filed periodic public reports with the SEC and the NASDAQ;
- (c) Ocugen regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases

on national circuits of major newswire services, and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Ocugen was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

273. Based on the foregoing, during the Class Period, the market for Ocugen securities promptly digested information regarding the Company from all publicly available sources and incorporated such information into the price of Ocugen securities. Under these circumstances, the market for Ocugen securities was efficient during the Class Period and, therefore, investors' purchases of Ocugen securities at artificially inflated market prices give rise to a class-wide presumption of reliance under the fraud-on-the-market doctrine.

274. In the alternative, the *Affiliated Ute* presumption of reliance applies to the extent that Defendants' statements during the Class Period involved omission of material facts. These omissions concealed, among other things, and as alleged more fully above, that because (unbeknownst to investors) Defendants were not complying with FDA Industry Guidance (a) an EUA pathway for COVAXIN authorization in the U.S. was extremely unlikely and the Company would need to pursue FDA approval of COVAXIN through a BLA, which would delay any FDA approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest and (b) whether seeking FDA authorization via an EUA or approval via a BLA, Ocugen would be required to first undertake U.S. trials of COVAXIN, which would delay any FDA authorization/approval and distribution of COVAXIN in the U.S. until late 2022, at the earliest.

275. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business and prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

IX. NO SAFE HARBOR

276. The statutory safe harbor or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint. None of the statements complained of herein was entirely a forward-looking statement. Rather, each statement was a statement of purportedly historical or current facts and conditions, and/or included a component of purportedly historical or current facts and conditions, and/or omitted material historical or current facts and conditions necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

277. To the extent that any of the false and misleading statements alleged herein can be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As set forth above in detail, then-existing facts undermined and contradicted the statements by the Defendants regarding Ocugen's business, operations, and expectations (including the prospects for the FDA authorization of COVAXIN and timing therefor), among others. Given the then-existing facts undermining and contradicting the statements by the Defendants, any generalized risk disclosures made by Ocugen were not sufficient to insulate the Defendants from liability for their materially false and misleading statements.

278. Further, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those statements was made, the particular speaker knew that the particular forward-looking statement was false, and the false forward-looking statement was authorized and approved by executive(s) or director(s) of Ocugen who knew the statement was false when made.

X. CLASS ACTION ALLEGATIONS

279. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all persons who purchased or otherwise acquired Ocugen securities during the Class Period (that is, between February 2, 2021 and June 9, 2021, inclusive). Excluded from the Class are Defendants and members of their immediate families, Company officers and directors and members of its Vaccine Scientific Advisory Board, at all relevant times, and members of their immediate families, the legal representatives, heirs, successors or assigns of any of the foregoing, and any entity in which Defendants have or had a controlling interest.

280. The members of the Class are so numerous that joinder of all members is impracticable. Ocugen reported in its May 7, 2021 Form 10-Q that there were more than 198 million public shares of Ocugen common stock issued and outstanding. Moreover, throughout the Class Period, Ocugen securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Ocugen or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

281. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

282. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

283. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether the Exchange Act was violated by Defendants as alleged herein;
- (b) whether statements made by Defendants misrepresented material facts about Ocugen's business and prospects; and
- (c) to what extent the members of the Class have sustained damages and the proper measure of damages.

284. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XI. CAUSES OF ACTION

COUNT I

For Violation of § 10(b) of the Exchange Act and SEC Rule 10b-5 Against All Defendants

285. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

286. This Count is asserted on behalf of all members of the Class against defendants Ocugen, Musunuri, and Forrest for violations of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

287. During the Class Period, defendants Ocugen, Musunuri, and Forrest disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

288. Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Ocugen securities during the Class Period.

289. Defendants, individually and together, directly and indirectly, by the use, means of instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal the truth and/or adverse material information about Ocugen's operations, business, and prospects, as specified herein.

290. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them.

291. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Ocugen securities. Plaintiff and the Class would not have purchased Ocugen securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Ocugen, Musunuri and Forrest's materially false and misleading statements.

292. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Ocugen securities during the Class Period.

COUNT II

For Violation of § 20(a) of the Exchange Act Against the Individual Defendants

293. Plaintiff repeats and realleges each and every allegation above as if fully set forth herein.

294. This Count is asserted on behalf of all members of the Class against defendants Musunuri and Forrest for violations of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

295. During the Class Period, each of the Individual Defendants was a controlling person of Ocugen within the meaning of § 20(a) of the Exchange Act. By reason of their high-level and influential positions with Ocugen and their participation in and/or awareness of the Company's operations and regulatory efforts, and/or intimate knowledge of the materially false or misleading statements and omissions of material fact in statements made by the Company and/or disseminated to the investing public, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company and its executives, including the content and dissemination of the various statements that Plaintiff contends were materially false or misleading.

296. Each of the Individual Defendants directly or indirectly exercised control over the Company and had the power and authority to cause Ocugen to engage in the wrongful conduct complained of herein. In this regard, each of the Individual Defendants was provided with or had access to copies of the Company's reports, presentations, press releases, public filings, and other statements alleged by Plaintiff to be materially misleading prior to and/or shortly after these

statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

297. Each of the Individual Defendants was a direct participant in making, and/or made aware of the circumstances surrounding, the materially false or misleading representations and omissions during the Class Period. Accordingly, each Individual Defendant was a culpable participant in the underlying violations of § 10(b) alleged herein.

298. As set forth above, Ocugen violated § 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Ocugen and, as a result of their own aforementioned conduct, each of the Individual Defendants is liable pursuant to § 20(a) of the Exchange Act, jointly and severally with, and to the same extent as Ocugen is liable under § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiff and other members of the Class who purchased or otherwise acquired Ocugen securities during the Class Period at artificially inflated prices.

299. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Ocugen securities during the Class Period.

COUNT III

For Violation of § 10(b) and § 20A of the Exchange Act and SEC Rule 10b-5 for Insider Trading Against Musunuri

300. Plaintiff repeats and realleges each and every allegation above as if fully set forth herein.

301. This Count is asserted for violations of § 20A of the Exchange Act, 15 U.S.C. § 78t-1(a) on behalf of Plaintiff and all other members of the Class who purchased shares of Ocugen

common stock contemporaneously with the sales of Ocugen common stock by Musunuri while he was in possession of material non-public information (“MNPI”) as alleged herein.

302. Section 20A(a) of the Exchange Act provides that “[a]ny person who violates any provision of the [Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class.”

303. Musunuri violated Exchange Act § 10(b) and Rule 10b-5 for the reasons stated in Count I above. Additionally, Musunuri violated Exchange Act § 10(b), Rule 10b-5, and Rule 10b5-1 (17 C.F.R. § 240.10b5-1) by selling shares of Ocugen common stock while in possession of MNPI concerning, among other things, Ocugen’s regulatory path for FDA authorization of COVAXIN and its failure to follow FDA guidance, as alleged herein, which information he had a duty to disclose, and which he failed to disclose in violation of § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

304. Contemporaneously with Musunuri’s insider sales of Ocugen common stock on May 3, 2021, Plaintiff purchased shares of Ocugen common stock on a national securities exchange while Musunuri was in possession of adverse MNPI as alleged herein.

305. Other Class members also purchased shares of Ocugen common stock contemporaneously with Musunuri’s insider sales of Ocugen common stock.

306. Plaintiff and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

307. By reason of the violations of the Exchange Act alleged herein, Musunuri is liable to Plaintiff and other members of the Class who purchased shares of Ocugen common stock contemporaneously with his sales of Ocugen common stock during the Class Period.

308. Plaintiff and the other members of the Class who purchased contemporaneously with Musunuri's insider sales of Ocugen securities sales seek disgorgement of profits gained from his transactions in Ocugen common stock contemporaneous with Plaintiff and other members of the Class.

309. This action was brought within five years after the date of the last transaction that is the subject of Musunuri's violation of § 20A, and, with respect to the underlying violations of § 10(b) of the Exchange Act alleged in this Count and in Count I above, was brought within five years after the date of the last transaction that violated § 20A of the Exchange Act by Musunuri.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying Plaintiff as Class representative under Rule 23 of the Federal Rules of Civil Procedure, and designating Lead Counsel as Class Counsel;

B. Awarding Plaintiff and other members of the Class damages together with interest thereon;

C. Ordering the disgorgement of all profits realized by Musunuri through his insider sales of Ocugen common stock at artificially inflated prices while in possession MNPI;

D. Awarding Plaintiff and other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees, expert fees, and other costs and disbursements; and

E. Awarding Plaintiff and other members of the Class such other and further relief as the Court deems just and proper under the circumstances.

XIII. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: June 13, 2022

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